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RESPIRATORY CARE

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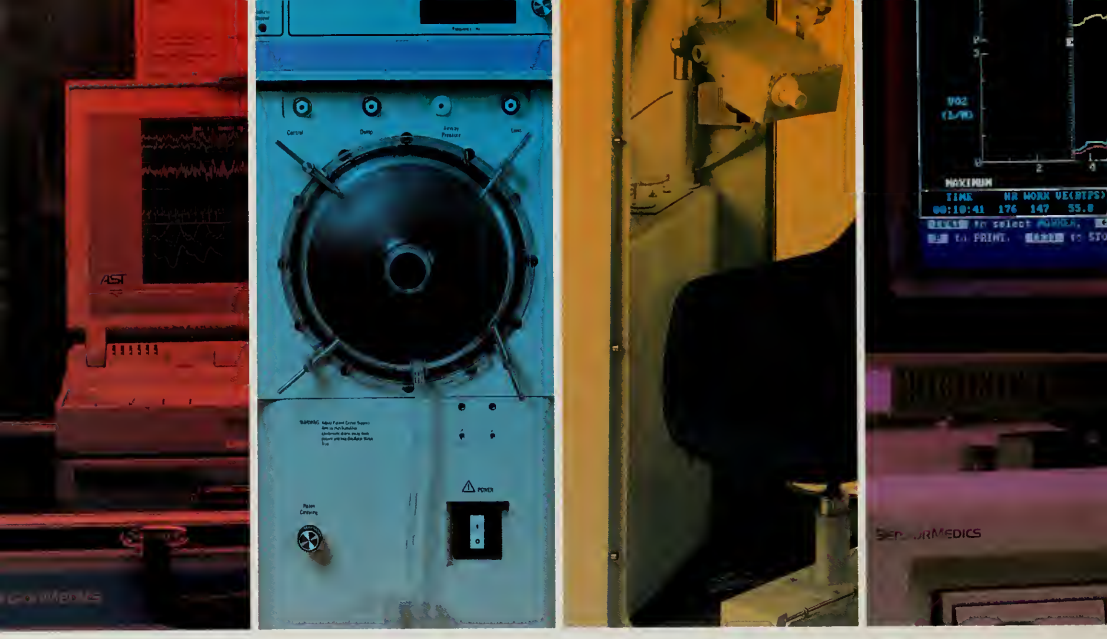

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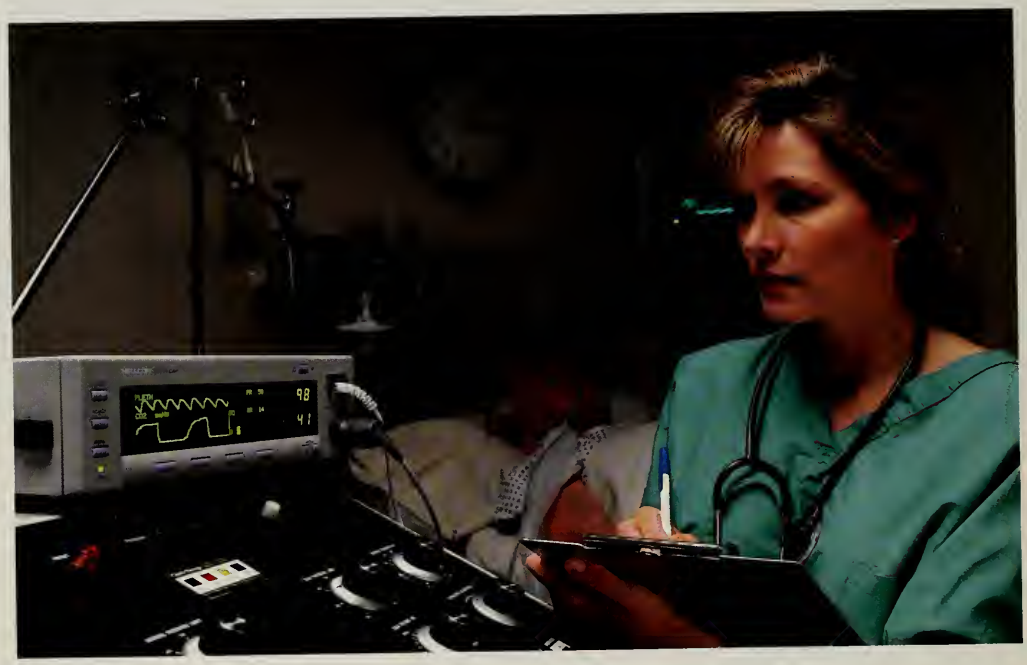

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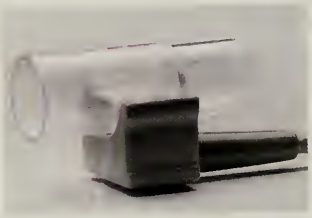

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Control of Tuberculosis in the United States (statement)—A joint statement of the American Thoracic Society, The American Academy of Pediatrics, The Centers for Disease Control and Prevention, and The Infectious Disease Society of America. Am Rev Respir Dis 1992;146: 1623-1633.

A Nurse-Directed Protocol Using Pulse Oximetry To Wean Mechanically Ventilated Patients from Toxic Oxygen Concentrations—LC Rotello, J Warren, MS Jastremski, A Milewski. Chest 1992;102:1833.

The usual method of weaning mechanically ventilated patients from high F_{IO_2} in our ICU, in which housestaff ordered all ventilator changes in an unstandardized manner (control group), was compared to a nurse-directed protocol that used a single arterial blood gas (ABG) analysis and multiple pulse oximetry measurements. The protocol required an ABG to be obtained upon the initiation of intubation/mechanical ventilation, followed by pulse oximetry measurements obtained in accordance with a standardized timetable. Decreases in F_{IO_2} were guided by these results. It was concluded that a nurse-directed oxygen weaning protocol utilizing a combination of a single ABG and multiple pulse oximetry measurements was safe, reduced the need for ABGs, and decreased the duration of patient exposure to toxic oxygen concentrations.

Pattern of Non-ICU Inpatient Supplemental Oxygen Utilization in a University Hospital—RJ Albin, GJ Criner, S Thomas, S Abou-Jaoude. Chest 1992;102:1672.

Random assessments of S_{aO_2} were performed via pulse oximetry in 274 hospitalized non-ICU patients prescribed supplemental O_2 in a large tertiary care university hospital. In 507 assessments performed in patients inspiring the prescribed O_2, 426 were receiving excessive amounts of O_2 to maintain a $S_{aO_2} \geq 92\%$. In 233 of these assessments, S_{aO_2} was $\geq$ 92% while breathing ambient air. In an additional 193 assessments, the concentration of inspired supplemental O_2 was excessive to maintain a S_{aO_2}, $\geq$ 92%. However, in 81 assessments performed in patients inspiring O_2, the prescribed amount was insufficient to maintain $S_{aO_2} \geq$ 92%. These results indicate that O_2 prescription in hospitalized non-ICU patients is excessive or not required in the majority of cases. Furthermore, routine use of pulse oximetry in hospitalized patients prescribed O_2 may be useful in determining the continued need for supplemental O_2 and adjusting the proper concentration needed to avoid hypoxemia.

Reproducibility of Weaning Parameters: A Need for Standardization—KL Yang. Chest 1992;102: 1829. *Related Editorial: Mador MJ. Weaning Parameters—Are They Clinically Useful? Chest 1992;102: 1642.*

Although weaning parameters can accurately predict weaning outcome, variability of the measurements of these parameters has not been closely examined. In the current study, we examined the reproducibility of these parameters using a standardized technique. Before the weaning trial, maximal inspiratory pressure (P_{Imax}), minute ventilation ($\dot{V}_E$), respiratory frequency (f), tidal volume (V_T), rapid shallow breathing index (f/V_T), and vital capacity (VC) were obtained in three trials over a period of 15 min. The results of these parameters over three measurements

were compared. There were no statistical differences in the values of P_{1max}, $\dot{V}_E$, f, V_T, and f/V_T over three trials ($p = 0.45$, $p = 0.37$, $p = 0.69$, $p = 0.64$, $p = 0.1$, respectively). The VC was the only parameter that showed statistical differences among three trials ($p < 0.05$). For the group, respiratory frequency had the lowest coefficient of variation (COV = SD/mean × 100%) at 6.7% while the VC had the highest COV at 19.6%. We concluded that most weaning parameters of breathing pattern can be measured reliably with bedside instruments using a standard technique.

Effect of Tidal Volume on Gas Exchange and Oxygen Transport in the Adult Respiratory Distress Syndrome—R Kiiski, J Takala, A Kari, J Milic-Emili. Am Rev Respir Dis 1992;146:1131.

The effect of tidal volume (V_T) on gas exchange and oxygen delivery ($\dot{D}_{O_2}$) was studied in 9 patients with adult respiratory distress syndrome (ARDS) and in 10 postoperative open-heart surgery patients (CABG). During controlled mechanical ventilation, V_T was initially 10 to 12 mL/kg, followed by an increase and reduction of 25% (1.25 V_T and 0.75 V_T, respectively). In both groups of patients, dead space (V_D) correlated strongly with V_T ($p < 0.001$), while the V_D/V_T ratio was independent of V_T. P_{aO_2} tended to increase in CABG patients and decrease in ARDS patients at 1.25 V_T. Arterial oxygen saturation (S_{aO_2}) did not change at 1.25 V_T but decreased at 0.75 V_T ($p < 0.001$) in the ARDS group. Venous admixture ($\dot{Q}_s/\dot{Q}_t$) decreased with 1.25 V_T and increased with 0.75 V_T ($p < 0.001$). A relatively larger increase in cardiac output compensated for the increased $\dot{Q}_s/\dot{Q}_t$ and the reduced S_{aO_2}, resulting in significantly higher $\dot{D}_{O_2}$ with 0.75 V_T ($p < 0.01$). A lower V_T resulted in improved balance between pulmonary gas exchange and whole body oxygen supply.

Genetic Influence on Smoking: A Study of Male Twins—D Carmelli, GE Swan, D Robinette, R Fabsitz. N Engl J Med 1992;327:829. *Related Editorial: Benowitz NL. The Genetics of Drug Dependence. N Engl J Med 1992;327:881.*

BACKGROUND: The results of twin and family studies suggest that heredity has a small influence on smoking behavior. METHODS: We conducted a genetic analysis of several aspects of smoking behavior among subjects in the National Academy of Sciences-National Research Council Twin Registry. The registry includes male twins who were born in the United States between 1917 and 1927 and who were members of the armed forces during World War II. Information on smoking history was available for 4,775 pairs of twins, who were first surveyed in 1967-1969, when they were 40 to 50 years old, and then resurveyed in 1983-1985, when they were 56 to 66. 80% of the subjects in this cohort had smoked at some time in their lives, 60% were smokers in 1967-1969, and 39% were smoking in 1983-1985. Similarities between twins in smoking habits at baseline and at the second follow-up 16 years later were examined. The comparison of concordance for smoking between monozygotic and dizygotic twins was used to assess the relative contribution of familial and genetic factors. RESULTS: In the 1967-1969 survey, the ratio of observed to expected concordance for smoking was higher among the monozygotic twins than among the dizygotic twins for those who had never smoked (overall rate ratio 1.38; 95% confidence interval 1.25-1.54), for former smokers (overall rate ratio 1.59; 95% confidence interval 1.5-1.85), for current cigarette smokers (overall rate ratio 1.18; 95% confidence interval 1.11-1.26), and for current cigar or pipe smokers (overall rate ratio 1.60; 95% confidence interval 1.22-2.06). The data also suggest genetic influences on quitting smoking. Monozygotic twins were more likely than dizygotic twins to be concordant for quitting smoking (overall rate ratio 1.24; 95% confidence interval 1.06-1.45). CONCLUSIONS: In this cohort of adult male twins, there were moderate genetic influences on lifetime smoking practices.

Use of a Measurement of Pulmonary Hyperinflation To Control the Level of Mechanical Ventilation in Patients with Acute Severe Asthma—DV Tuxen, TJ Williams, CD Scheinkestel, D Czarny, G Bowes. Am Rev Respir Dis 1992;146:1136.

Mechanical ventilation causes significant morbidity and mortality in patients with severe asthma. Hypoventilation may reduce this morbidity and mortality, but indicators to guide the degree of hypoventilation are unclear. We used a measure of pulmonary hyperinflation to assess the degree of airflow obstruction and to guide the extent and duration of hypoventilation. Ten patients who required mechanical ventilation for acute severe asthma were studied. All were sedated, paralyzed, and given an initial minute ventilation ($\dot{V}_E$) of 200 mL/kg/min. End-inspiratory lung volume (V_{EI}) above FRC was measured from the total exhaled gas volume during 40 to 60 seconds of apnea. V_{EI} was used to regulate $\dot{V}_E$ to a safe level ($\dot{V}_{Esafe}$), irrespective of P_{aCO_2}, by reducing the rate when V_{EI} was > 20 mL/kg and increasing it when V_{EI} was < 20 mL/kg. Each patient was weaned when $\dot{V}_{Esafe}$ resulted in $P_{aCO_2} \leq 40$ torr (the weaning point). FRC was measured by com-

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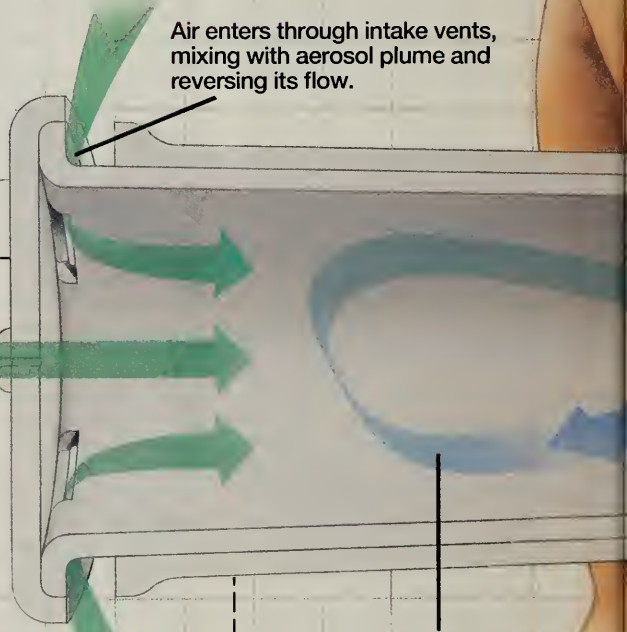
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puter analysis of anterior and lateral chest radiographs taken at the end of apnea. Using the weaning point criterion, 2 patients (P_{aCO_2} < 40 torr) were weaned shortly after arrival. The remaining 8 (initial P_{aCO_2} 63 ± 17 torr) continued hypoventilation until the weaning point was reached (30 ± 29 h). The weaning point was reached by the $\dot{V}_E$ required for P_{aCO_2} 40 torr decreasing concurrent with the $\dot{V}_{Esafe}$ increasing. All but 1 patient were successfully weaned within 24 h of the weaning point. Initial FRC was elevated (4.8 ± 1.9 L; predicted 3.2 ± 0.3 L; p = 0.06) and decreased in parallel with V_{EI} when airflow obstruction had improved at the weaning point. FRC showed a high level of correlation with V_{EI} (r = 0.85, p < 0.001). In conclusion, V_{EI} was a valuable indicator of the severity of airflow obstruction and the level of FRC. V_{EI} provided a reliable guide to the extent of hypoventilation and the duration of mechanical ventilation.

Impairment of Airway Mucociliary Transport by *Pseudomonas aeruginosa* Products: Role of Oxygen Radicals—ZV Seybold, WM Abraham, H Gazeroglu, A Wanner. Am Rev Respir Dis 1992;146:1173.

We previously showed that the supernatant of a *Pseudomonas aeruginosa* (PA) culture and its constituents pyocyanin and 1-hydroxyphenazine inhibit ciliary activity of dispersed tracheal epithelial cells in vitro via the generation of oxygen radicals by phagocytes. In the present study, we wished to determine if tracheal mucus velocity (TMV) is also impaired by PA supernatant and if oxygen radicals have a mediating role. In conscious sheep, TMV (measured with a radiographic method) was determined before and serially following aerosol challenge with the cell-free supernatant of a PA culture or unconditioned culture medium (control). TMV decreased from a mean (± SEM) baseline of 6.7 ± 1.1 mm/min (n = 6) by 29, 35, and 25% at 0.5, 3, and 24 h after challenge, respectively (p < 0.05), and returned to baseline 1 wk later (–6%, p = NS). Control medium had no effect on TMV (maximum decrease by 15% at 0.5 h). Aerosolized catalase blunted the effect of PA supernatant on TMV. To determine if the impairment of TMV involved ciliary inhibition, tissues were mounted in a chamber and ciliary beat frequency (CBF) and surface liquid velocity (SLV) were measured with a microscopic method. PA supernatant decreased both CBF (maximum mean decrease 12%; n = 5, p < 0.05) and SLV (maximum mean decrease 78%; n = 5, p < 0.05) in a dose-dependent fashion, with a correlation between the two parameters; these effects were blocked by catalase. We conclude that (1) short-term exposure to PA products decreases airway mucociliary clearance in vivo in part by a pathway involving oxygen radicals, (2) the impairment persists for at least 24 h but less than a week, and (3) cilio-inhibition has a role in the PA-induced decrease in mucociliary clearance.

Dissociation between Dyspnea and Respiratory Effort—BH Demediuk, H Manning, J Lilly, V Fencl, SE Weinberger, JW Weiss, RM Schwartzstein. Am Rev Respir Dis 1992;146:1222.

Breathlessness induced by hypercapnia may be related to the sensation of respiratory effort or to the central or peripheral effects of CO_2. To examine the relationship among breathlessness, respiratory effort, and hypercapnia, we studied 8 normal naive subjects. By using a visual feedback system, subjects maintained a constant ventilation of 50-60 L/min. P_{etCO_2} was held at 40 torr during the first 2 min of each trial (control period), then for 4 min (test period) was either kept at 40 torr or elevated to 50 torr. At the end of each control and test period, subjects were asked to give separate ratings for dyspnea (an unpleasant urge to breathe) and for the sense of respiratory effort (analogous to lifting a weight) on a 50-cm visual analog scale. Hypercapnia was associated with a significant reduction in effort ratings (–7.3 ± 6.4, mean ± SD, p < 0.05) and a concomitant increase in dyspnea (+6.6 ± 6.0, p < 0.05). We conclude that dyspnea associated with hypercapnia is dissociated from changes in respiratory effort, and that CO_2 has a direct central effect that leads to breathlessness. Our data also suggest that the sense of effort at a given level of ventilation is less when the ventilation is the result of "reflex" stimuli to breathe rather than "voluntary" signals to the respiratory muscles.

Comparison of Six Oxygen Delivery Systems for COPD Patients at Rest and during Exercise—SR Braun, G Spratt, GC Scott, M Ellersieck. Chest 1992;102:694.

Five different oxygen-conserving devices were tested in each of 10 oxygen-dependent patients with COPD who had met the NOTT criteria for continuous oxygen use. They were tested on room air, their prescribed continuous oxygen flow, and then on each of the 5 devices. The devices that delivered a bolus of oxygen during early inspiration or increased oxygen delivery as the respiratory rate increased did better than those devices that delivered oxygen at a normal flowrate during inspiration or a fixed portion of inspiration. In at least one of the subjects, each device was associated with desaturation to less than 80% during a 12-min walk. It is concluded that oxygen-conserv-

SURVANTA®

beractant
intratracheal suspension
bovine pulmonary surfactant

From Ross Laboratories—
Helping Premature Babies Survive™

Please see adjacent column for Brief Summary of prescribing information.

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BRIEF SUMMARY: Please see package insert for full prescribing information.

SURVANTA® (1040)

beractant

intratracheal suspension

Sterile Suspension/For Intratracheal Use Only

INDICATIONS AND USAGE

SURVANTA is indicated for prevention and treatment ("rescue") of Respiratory Distress Syndrome (RDS) (hyaline membrane disease) in premature infants. SURVANTA significantly reduces the incidence of RDS, mortality due to RDS and air leak complications.

Prevention

In premature infants less than 1250 g birth weight or with evidence of surfactant deficiency, give SURVANTA as soon as possible, preferably within 15 minutes of birth.

Rescue

To treat infants with RDS confirmed by x-ray and requiring mechanical ventilation, give SURVANTA as soon as possible, preferably by 8 hours of age.

CONTRAINDICATIONS

None known.

WARNINGS

SURVANTA is intended for intratracheal use only.

SURVANTA CAN RAPIDLY AFFECT OXYGENATION AND LUNG COMPLIANCE. Therefore, its use should be restricted to a highly supervised clinical setting with immediate availability of clinicians experienced with intubation, ventilator management, and general care of premature infants. Infants receiving SURVANTA should be frequently monitored with arterial or transcutaneous measurement of systemic oxygen and carbon dioxide.

DURING THE DOSING PROCEDURE, TRANSIENT EPISODES OF BRADYCARDIA AND DECREASED OXYGEN SATURATION HAVE BEEN REPORTED. If these occur, stop the dosing procedure and initiate appropriate measures to alleviate the condition. After stabilization, resume the dosing procedure.

PRECAUTIONS

General

Rales and moist breath sounds can occur transiently after administration. Endotracheal suctioning or other remedial action is not necessary unless clear-cut signs of airway obstruction are present.

Increased probability of post-treatment nosocomial sepsis in SURVANTA-treated infants was observed in the controlled clinical trials (Table 3). The increased risk for sepsis among SURVANTA-treated infants was not associated with increased mortality among these infants. The causative organisms were similar in treated and control infants. There was no significant difference between groups in the rate of post-treatment infections other than sepsis.

Use of SURVANTA in infants less than 600 g birth weight or greater than 1750 g birth weight has not been evaluated in controlled trials. There is no controlled experience with use of SURVANTA in conjunction with experimental therapies for RDS (eg, high-frequency ventilation or extracorporeal membrane oxygenation).

No information is available on the effects of doses other than 100 mg phospholipids/kg, more than four doses, dosing more frequently than every 6 hours, or administration after 48 hours of age.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Reproduction studies in animals have not been completed. Mutagenicity studies were negative. Carcinogenicity studies have not been performed with SURVANTA.

ADVERSE REACTIONS

The most commonly reported adverse experiences were associated with the dosing procedure. In the multiple-dose controlled clinical trials, transient bradycardia occurred with 11.9% of doses. Oxygen desaturation occurred with 9.8% of doses.

Other reactions during the dosing procedure occurred with fewer than 1% of doses and included endotracheal tube reflux, pallor, vasoconstriction, hypotension, endotracheal tube blockage, hypertension, hypocarbia, hypercarbia, and apnea. No deaths occurred during the dosing procedure, and all reactions resolved with symptomatic treatment.

The occurrence of concurrent illnesses common in premature infants was evaluated in the controlled trials. The rates in all controlled studies are in Table 3.

TABLE 3

	All Controlled Studies		
Concurrent Event	**SURVANTA (%)**	**Control (%)**	***P*-Value[a]**
Patent ductus arteriosus	46.9	47.1	0.814
Intracranial hemorrhage	48.1	45.2	0.241
Severe intracranial hemorrhage	24.1	23.3	0.693
Pulmonary air leaks	10.9	24.7	<0.001
Pulmonary interstitial emphysema	20.2	38.4	<0.001
Necrotizing enterocolitis	6.1	5.3	0.427
Apnea	65.4	59.6	0.263
Severe apnea	46.1	42.5	0.114
Post-treatment sepsis	20.7	16.1	0.019
Post-treatment infection	10.2	9.1	0.345
Pulmonary hemorrhage	7.2	5.3	0.166

[a]*P*-value comparing groups in controlled studies

When all controlled studies were pooled, there was no difference in intracranial hemorrhage. However, in one of the single-dose rescue studies and one of the multiple-dose prevention studies, the rate of intracranial hemorrhage was significantly higher in SURVANTA patients than control patients (63.3% *v* 30.8%, $P = 0.001$; and 48.8% *v* 34.2%, $P = 0.047$, respectively). The rate in a Treatment IND involving approximately 4400 infants was lower than in the controlled trials.

In the controlled clinical trials, there was no effect of SURVANTA on results of common laboratory tests: white blood cell count and serum sodium, potassium, bilirubin, creatinine.

More than 3700 pretreatment and post-treatment serum samples were tested by Western Blot immunoassay for antibodies to surfactant-associated proteins SP-B and SP-C. No IgG or IgM antibodies were detected.

Several other complications are known to occur in premature infants. The following conditions were reported in the controlled clinical studies. The rates of the complications were not different in treated and control infants, and none of the complications were attributed to SURVANTA.

Respiratory: lung consolidation, blood from the endotracheal tube, deterioration after weaning, respiratory decompensation, subglottic stenosis, paralyzed diaphragm, respiratory failure.

Cardiovascular: hypotension, hypertension, tachycardia, ventricular tachycardia, aortic thrombosis, cardiac failure, cardiorespiratory arrest, increased apical pulse, persistent fetal circulation, air embolism, total anomalous pulmonary venous return.

Gastrointestinal: abdominal distention, hemorrhage, intestinal perforations, volvulus, bowel infarct, feeding intolerance, hepatic failure, stress ulcer.

Renal: renal failure, hematuria.

Hematologic: coagulopathy, thrombocytopenia, disseminated intravascular coagulation.

Central Nervous System: seizures.

Endocrine/Metabolic: adrenal hemorrhage, inappropriate ADH secretion, hyperphosphatemia.

Musculoskeletal: inguinal hernia.

Systemic: fever, deterioration.

Follow-Up Evaluations

To date, no long-term complications or sequelae of SURVANTA therapy have been found.

Single-Dose Studies

Six-month adjusted-age follow-up evaluations of 232 infants (115 treated) demonstrated no clinically important differences between treatment groups in pulmonary and neurologic sequelae, incidence or severity of retinopathy of prematurity, rehospitalizations, growth, or allergic manifestations.

Multiple-Dose Studies

Six-month adjusted age follow-up evaluations have not been completed. Preliminarily, in 605 (333 treated) of 916 surviving infants, there are trends for decreased cerebral palsy and need for supplemental oxygen in SURVANTA infants. Wheezing at the time of examination tended to be more frequent among SURVANTA infants, although there was no difference in bronchodilator therapy.

Twelve-month follow-up data from the multiple-dose studies have been completed in 328 (171 treated) of 909 surviving infants. To date no significant differences between treatments have been found, although there is a trend toward less wheezing in SURVANTA infants in contrast to the six month results.

OVERDOSAGE

Overdosage with SURVANTA has not been reported. Based on animal data, overdosage might result in acute airway obstruction. Treatment should be symptomatic and supportive.

Rales and moist breath sounds can transiently occur after SURVANTA is given, and do not indicate overdosage. Endotracheal suctioning or other remedial action is not required unless clear-cut signs of airway obstruction are present.

HOW SUPPLIED

SURVANTA (beractant) Intratracheal Suspension is supplied in single-use glass vials containing 8 mL of SURVANTA (NDC 0074-1040-08). Each milliliter contains 25 mg of phospholipids (200 mg phospholipids/8 mL) suspended in 0.9% sodium chloride solution. The color is off-white to light brown.

Store unopened vials at refrigeration temperature (2-8°C). Protect from light. Store vials in carton until ready for use. Vials are for single use only. Upon opening, discard unused drug.

June, 1991

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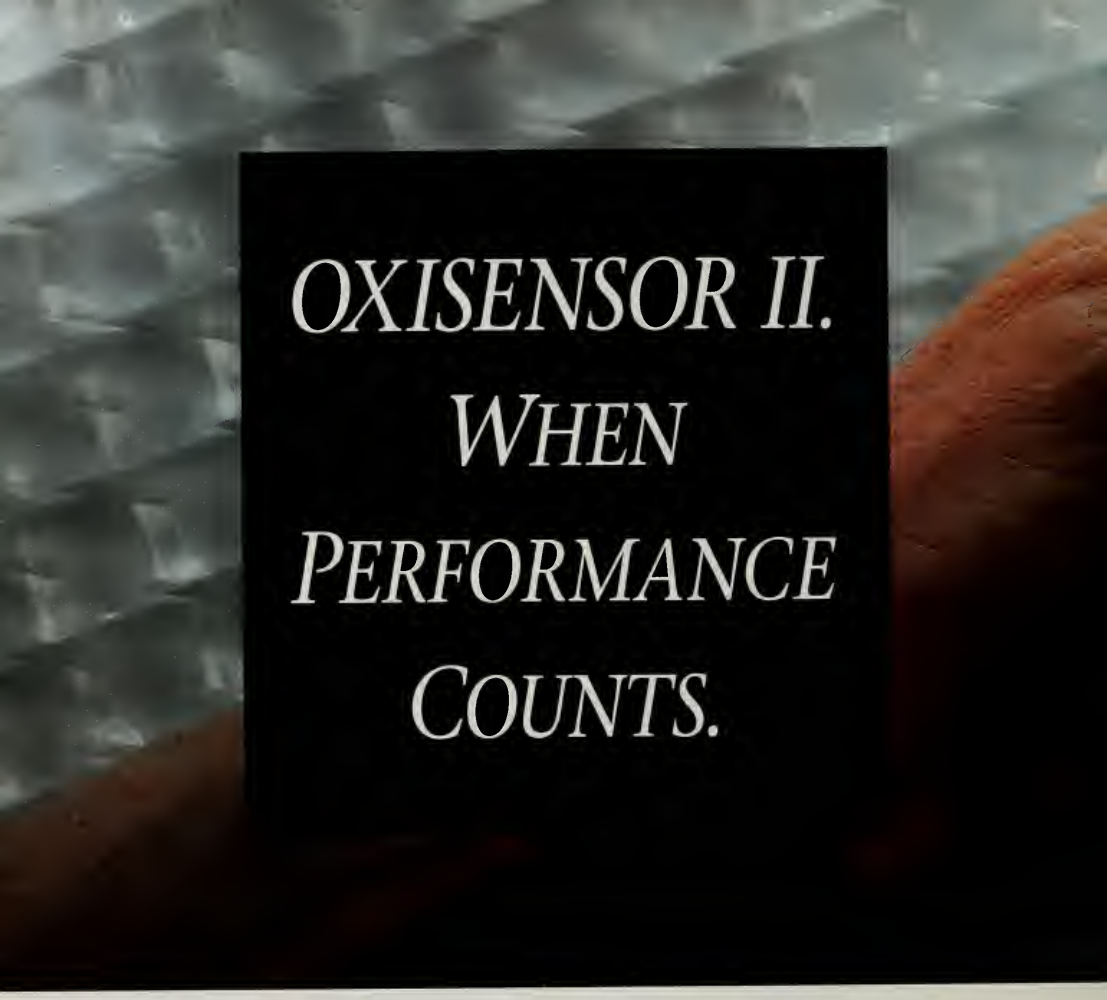

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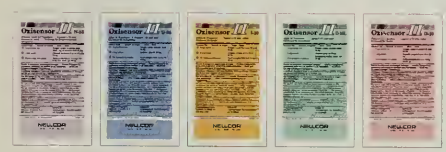

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ing devices vary in their ability to maintain S_{aO_2} levels during exercise. It is recommended that a home oxygen evaluation include measurement of an exercise S_{aO_2} utilizing the prescribed oxygen delivery system.

Breathlessness in Patients with Severe Chronic Airflow Limitation: Physiologic Correlations—DE O'Donnell, KA Webb. Chest 1992;102:824.

We wished to identify the physiologic abnormalities that distinguish severely breathless (SB) patients with chronic airflow limitation (CAL) from mildly breathless (MB) patients. 37 patients with stable, advanced CAL ($FEV_1 = 38 \pm 10\%$ predicted, mean ± SD) were separated into 2 distinct groups, SB and MB, solely on the basis of their baseline dyspnea index (BDI). BDI ratings in SB (n = 17) and MB (n = 20) patients were 2.5 ± 1.5 and 8.5 ± 1.5 (mean ± SD), respectively ($p < 0.001$). Groups were compared with respect to pulmonary function, breathing pattern parameters, arterial blood gases (ABGs), and responses to progressive exercise. Steady-state gas-exchange parameters were measured in a subgroup of 16 patients during exercise. There were no significant intergroup differences in dynamic flows, plethysmographic lung volumes, ABGs, resting ventilation, or breathing pattern parameters. However, the SB group had significantly lower single-breath diffusing capacities for carbon monoxide (D_{CO}) (by an average of 50%, $p < 0.001$), together with significantly higher resting ventilatory equivalents for carbon dioxide ($\dot{V}_E/\dot{V}_{CO_2}$) (by 17%, $p < 0.01$) and dead-space-to-tidal-volume ratios (by 11%, $p < 0.05$). Ventilatory responses for a given metabolic load were, on average, 33% higher ($p < 0.05$) in the SB group reflecting greater ventilation-perfusion inhomogeneity and wasted ventilation. The SB subgroup (n = 7), in contrast to the MB subgroup (n = 9), demonstrated significantly ($p < 0.01$) greater O_2 desaturation during exercise; P_{aO_2} decreased in SB and MB at peak exercise by -13 ± 7 torr and -4 ± 2 torr (mean ± SD), respectively. Stepwise regression analysis selected Dco and $\dot{V}_E/\dot{V}_{CO_2}$ as the only predictors of breathlessness in this group, accounting for 52% of the variance in BDI (F ratio = 18.49, $p < 0.001$). Although the origin of breathlessness is multifactorial, variation in its intensity among patients with comparable levels of airflow limitation can be accounted for, in part, by underlying pathophysiologic differences. Severely breathless patients were characterized by lower resting diffusing capacities and accelerated ventilatory responses to exercise.

Effects of Cigarette Smoking on Rate of Loss of Pulmonary Function in Adults: A Longitudinal Assessment—X Xu, DW Dockery, JH Ware, FE Speizer, BG Ferris Jr. Am Rev Respir Dis 1992;146:1345.

Data from a random sample of 8,191 men and women selected in six U.S. cities and examined on three occasions over a 6-y follow-up period were analyzed by longitudinal methods to describe the effects of smoking history and current smoking behavior on rate of loss of pulmonary function during adult life. Former smokers had age- and height-adjusted rates of decline (34.3 mL/y for men and 29.5 mL/y for women) comparable with those of never smokers (37.8 mL/y for men and 38.0 mL/y for women). The accelerated rate of loss of FEV_1 among smokers depended linearly on the number of cigarettes smoked per day during the interval between examinations. The estimated increase in rate of loss associated with smoking was 12.6 mL/y per pack/day for men and 7.2 mL/y per pack/day for women. These longitudinal estimates of the effects of smoking were approximately 50% larger than estimates obtained from cross-sectional analysis of the initial pulmonary function examination. Men who started smoking had accelerated rates of loss (55.9 mL/y) as did women (43.1 mL/y). Smokers who stopped smoking between examinations had reduced declines (41.2 mL/y for men and 28.7 mL/y for women) compared with continuing smokers. The age-specific rates of loss suggest that the benefits of cessation may be greatest among the youngest smokers. The changes associated with starting or cessation of smoking were much smaller than those found in cross-sectional analyses of these data. In summary, cigarette smoking causes an accelerated annual loss of pulmonary function that may be underestimated by cross-sectional studies. Those who stop smoking will experience only a small recovery in pulmonary function level, but they will cease to lose pulmonary function at an accelerated rate.

Effects of Surgical Correction of Nasal Obstruction in the Treatment of Obstructive Sleep Apnea—F Sériès, S St Pierre, G Carrier. Am Rev Respir Dis 1992;146:1261.

Negative upper airway pressure is thought to play a key role in the pathophysiology of obstructive sleep apnea. Because nasal resistance contributes to the increase of the transpharyngeal pressure gradient, we evaluated the effects of nasal surgery on sleep-related breathing abnormalities in 20 adults with obstructive sleep apnea. Polysomnographic studies were done before (baseline), and 2 to 3 mo after surgery (septoplasty, turbinectomy, and/or polypectomy). Nasal resistances were measured at these vis-

its in 14 patients. Cephalometric measurements were obtained before surgery. Cephalometric abnormalities consisted of an increase in the distance from the mandibular plane to the hyoid bone (MP-H), a decrease in the space between the base of the tongue and the posterior soft tissues (PAS), a retroposition of the mandible, and an increase in the length of the soft palate. Body weight did not change between the two studies. Nasal resistance decreased significantly after nasal surgery. The composition of the total sleep time spent in the rapid eye movement stage increased from 11.5 ± 1.3% (mean ± SEM) to 14 ± 1.2% after surgery. For the group as a whole, there was no difference between baseline and postsurgical values in the frequency of respiratory disturbances (39.8 ± 6.1, 36.8 ± 5.9 n/h), the total apnea time (17.8 ± 4.2, 15.4 ± 2.8), the distribution of the apnea time within the different apnea types (obstructive and nonobstructive), and the severity of the nocturnal desaturations. Interestingly, apnea and apnea plus hypopnea indices returned to normal values (< 5 and 10, respectively) in four subjects with normal posterior soft tissues and mandibular-plane-to-hyoid-bone distances. We conclude that nasal surgery has a limited efficacy in the treatment of adult sleep apnea patients. The importance of cephalometry in identifying subjects who may benefit from nasal surgery remains to be determined.

Care of the Pediatric Organ Donor—LW Brink, A Ballew. AJDC 1992; 146:1045.

Solid organ transplantation has become an accepted therapeutic option in pediatrics. Many previously fatal diseases have become current indications for organ transplantation. A major limitation to the growth of this therapeutic option is the availability of suitable organs. With organ supply falling far short of demand, recruitment of donors has been stressed. In addition to recruiting donors, physicians are responsible for maintaining optimal organ function in a beating heart organ donor to ensure that all organs that could potentially be harvested are in a condition suitable for transplant. Current information demonstrates numerous physiologic changes resulting from cerebral death. Therapeutic interventions must focus on maintenance of function in all potentially transplantable organs, including kidneys, heart, lungs, liver, and pancreas. Physicians should recognize the interventions that might compromise the use of an organ in transplant. Criteria for organ use are constantly changing, and the implications of different therapeutic interventions must still be evaluated.

Severe Laryngotracheobronchitis Complicating Measles—JD Fortenberry, MM Mariscalco, PT Louis, F Stein, JK Jones, LS Jefferson. AJDC 1992;146:1040.

OBJECTIVE: To determine the incidence of severe measles-related laryngotracheobronchitis in patients hospitalized during a recent measles epidemic and to evaluate factors associated with severity of airway injury and its management. DESIGN: Clinical description of patient series. SETTING: Children's hospital and county general hospital, Houston

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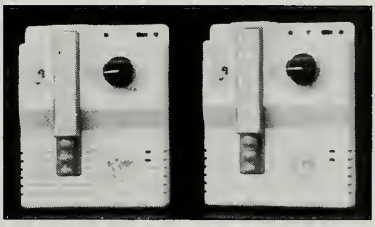

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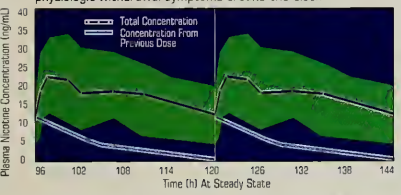

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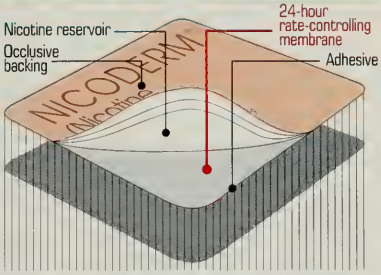

The special 24-hr "rate-controlling" membrane in Nicoderm

Not just physiological help, but psychological help, too
Nicoderm should only be used as part of a comprehensive behavioral smoking-cessation program. In addition, Nicoderm provides patients with the 6-2-2 Committed Quitter's book, an aid that helps them cope with the psychological and social aspects of quitting.

Nicoderm, the convenient solution
Because predictable patient compliance is so important, it's also reassuring to know that Nicoderm has the smallest dimensions of any nicotine patch available, with a superthin profile that avoids catching on clothes. Plus convenient 2-week packaging.
Once your patients decide to quit, help them avoid unpredictable withdrawal symptoms. Prescribe Nicoderm–a predictable, full-time nicotine patch.
Nicoderm is indicated as an aid to smoking cessation for the relief of nicotine withdrawal symptoms. Nicoderm should be used as part of a comprehensive behavioral smoking-cessation program. The use of Nicoderm beyond 3 months has not been studied. Patients should be instructed to **stop smoking immediately** and should not use any other nicotine-containing products during treatment.
The specific effects of Nicoderm on fetal development are unknown. Therefore, pregnant or nursing smokers should be encouraged to attempt cessation using educational and behavioral interventions before using pharmacological approaches. Marion Merrell Dow does not recommend use of Nicoderm in pregnant women. The risks of nicotine replacement in patients with certain cardiovascular and peripheral vascular diseases should be weighed against the benefits of including nicotine replacement in a smoking-cessation program for them. Dosage adjustment of concomitant medications may be necessary. (See Drug Interactions.)

Please see brief summary of prescribing information on an adjacent page

NICODERM

[nicotine transdermal system]

©1992, Marion Merrell Dow Inc. D971R2

Patch shown 60% of actual size

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Brief Summary of
Prescribing Information as of January 1992

NICODERM®
(nicotine transdermal system)

Systemic delivery of 21, 14, or 7 mg/day over 24 hours

Caution: Federal law prohibits dispensing without prescription

DESCRIPTION

NICODERM is a transdermal system that provides systemic delivery of nicotine for 24 hours following its application to intact skin.

The NICODERM system is a multilayered rectangular film containing nicotine as the active agent. For the three doses the composition per unit area is identical. Proceeding from the visible surface toward the surface attached to the skin are (1) an occlusive backing (polyethylene/aluminum/polyester/ethylene-vinyl acetate copolymer), (2) a drug reservoir containing nicotine (in an ethylene-vinyl acetate copolymer matrix), (3) a rate-controlling membrane (polyethylene), (4) a polyisobutylene adhesive and (5) a protective liner that covers the adhesive layer and must be removed before application to the skin.

INDICATIONS AND USAGE

NICODERM treatment is indicated as an aid to smoking cessation for the relief of nicotine withdrawal symptoms. NICODERM treatment should be used as part of a comprehensive behavioral smoking-cessation program.

The use of NICODERM systems for longer than 3 months has not been studied.

CONTRAINDICATIONS

Use of NICODERM systems is contraindicated in patients with hypersensitivity or allergy to nicotine or to any of the components of the therapeutic system.

WARNINGS

Nicotine from any source can be toxic and addictive. Smoking causes lung cancer, heart disease, and emphysema and may adversely affect the fetus and the pregnant woman. For any smoker, with or without concomitant disease or pregnancy, the risk of nicotine replacement in a smoking-cessation program should be weighed against the hazard of continued smoking while using NICODERM systems and the likelihood of achieving cessation of smoking without nicotine replacement.

Pregnancy Warning

Tobacco smoke, which has been shown to be harmful to the fetus, contains nicotine, hydrogen cyanide, and carbon monoxide. Nicotine has been shown in animal studies to cause fetal harm. It is therefore presumed that NICODERM systems can cause fetal harm when administered to a pregnant woman. The effect of nicotine delivery by NICODERM systems has not been examined in pregnancy (see PRECAUTIONS).

Therefore pregnant smokers should be encouraged to attempt cessation using educational and behavioral interventions before using pharmacological approaches. If NICODERM systems are used during pregnancy, or if the patient becomes pregnant while using NICODERM systems, the patient should be apprised of the potential hazard to the fetus.

Safety Note Concerning Children

The amounts of nicotine that are tolerated by adult smokers can produce symptoms of poisoning and could prove fatal if the NICODERM system is applied or ingested by children or pets. Used 21 mg/day systems contain about 73% (83 mg) of their initial drug content. Therefore, patients should be cautioned to keep both the used and unused NICODERM systems out of the reach of children and pets.

PRECAUTIONS

The patient should be urged to stop smoking completely when initiating NICODERM therapy (see DOSAGE AND ADMINISTRATION). Patients should be informed that if they continue to smoke while using NICODERM systems, they may experience adverse effects due to peak nicotine levels higher than those experienced from smoking alone. If there is a clinically significant increase in cardiovascular or other effects attributable to nicotine, the NICODERM dose should be reduced or NICODERM treatment discontinued (see WARNINGS). Physicians should anticipate that concomitant medications may need dosage adjustment (see Drug Interactions).

The use of NICODERM systems beyond 3 months by patients who stop smoking should be discouraged, because the chronic consumption of nicotine by any route can be harmful and addicting.

Allergic Reactions

In a 6-week, open-label, dermal irritation and sensitization study of NICODERM systems, 7 of 230 patients exhibited definite erythema at 24 hours after application. Upon rechallenge, 4 patients exhibited mild to moderate contact allergy. Patients with contact sensitization should be cautioned that a serious reaction could occur from exposure to other nicotine-containing products or smoking. In the efficacy trials, erythema following system removal was typically seen in about 14% of patients, some edema in 3%, and dropouts due to skin reactions occurred in 2% of patients.

Patients should be instructed to promptly discontinue the use of NICODERM systems and contact their physicians, if they experience severe or persistent local skin reactions (eg, severe erythema, pruritus or edema) at the site of application or a generalized skin reaction (eg, urticaria, hives, or generalized rash).

Patients using NICODERM therapy concurrently with other transdermal products may exhibit local reactions at both application sites. Reactions were seen in 2 of 7 patients using concomitant Estraderm® (estradiol transdermal system) in clinical trials. In such patients, use of one or both systems may have to be discontinued.

Skin Disease

NICODERM systems are usually well tolerated by patients with normal skin, but may be irritating for patients with some skin disorders (atopic or eczematous dermatitis).

Cardiovascular or Peripheral Vascular Diseases

The risks of nicotine replacement in patients with certain cardiovascular and peripheral vascular diseases should be weighed against the benefits of including nicotine replacement in a smoking-cessation program for them. Specifically, patients with coronary heart disease (history of myocardial infarction and/or angina pectoris), serious cardiac arrhythmias, or vasospastic diseases (Buerger's disease, Prinzmetal's variant angina) should be carefully screened and evaluated before nicotine replacement is prescribed.

Tachycardia occurring in association with the use of NICODERM therapy was reported occasionally. If serious cardiovascular symptoms occur with the use of NICODERM therapy, it should be discontinued.

NICODERM therapy was as well tolerated as placebo in a controlled trial in patients with coronary artery disease (see CLINICAL STUDIES). One patient on NICODERM 21mg/day, two on NICODERM 14 mg/day, and eight on placebo discontinued treatment due to adverse events.

NICODERM therapy did not affect angina frequency or the appearance of arrhythmias on Holter monitoring in these patients.

NICODERM therapy generally should not be used in patients during the immediate post-myocardial infarction period, patients with serious arrhythmias, and patients with severe or worsening angina pectoris.

Renal or Hepatic Insufficiency

The pharmacokinetics of nicotine have not been studied in the elderly or in patients with renal or hepatic impairment. However, given that nicotine is extensively metabolized and that its total system clearance is dependent on liver blood flow, some influence of hepatic impairment on drug kinetics (reduced clearance) should be anticipated. Only severe renal impairment would be expected to affect the clearance of nicotine or its metabolites from the circulation (see Pharmacokinetics).

Endocrine Diseases

NICODERM therapy should be used with caution in patients with hyperthyroidism, pheochromocytoma, or insulin-dependent diabetes, since nicotine causes the release of catecholamines by the adrenal medulla.

Peptic Ulcer Disease

Nicotine delays healing in peptic ulcer disease; therefore, NICODERM therapy should be used with caution in patients with active peptic ulcers and only when the benefits of including nicotine replacement in a smoking-cessation program outweigh the risks.

Accelerated Hypertension

Nicotine therapy constitutes a risk factor for development of malignant hypertension in patients with accelerated hypertension; therefore, NICODERM therapy should be used with caution in these patients and only when the benefits of including nicotine replacement in a smoking-cessation program outweigh the risks.

Information for Patient

A patient instruction booklet is included in the package of NICODERM systems dispensed to the patient. The instruction sheet contains important information and instructions on how to properly use and dispose of NICODERM systems. Patients should be encouraged to ask questions of the physician and pharmacist. Patients must be advised to keep both used and unused systems out of the reach of children and pets.

Drug Interactions

Smoking cessation, with or without nicotine replacement, may alter the pharmacokinetics of certain concomitant medications.

May Require To Decrease in Dose at Cessation of Smoking	Possible Mechanism
acetaminophen, caffeine, imipramine, oxazepam, pentazocine, propranolol, theophylline	Deinduction of hepatic enzymes on smoking cessation
insulin	Increase in subcutaneous insulin absorption with smoking cessation
adrenergic antagonists (eg, prazosin, labetalol)	Decrease in circulating catecholamines with smoking cessation

May Require an Increase in Dose at Cessation of Smoking	Possible Mechanism
adrenergic agonists (eg, isoproterenol, phenylephrine)	Decrease in circulating catecholamines with smoking cessation

Carcinogenesis, Mutagenesis, Impairment of Fertility

Nicotine itself does not appear to be a carcinogen in laboratory animals. However, nicotine and its metabolites increased the incidences of tumors in the cheek pouches of hamsters and forestomach of F344 rats, respectively, when given in combination with tumor initiators. One study, which could not be replicated, suggested that cotinine, the primary metabolite of nicotine, may cause lymphoreticular sarcoma in the large intestine in rats.

Nicotine and cotinine were not mutagenic in the Ames *Salmonella* test. Nicotine induced repairable DNA damage in an *E. coli* test system. Nicotine was shown to be genotoxic in a test system using Chinese hamster ovary cells. In rats and rabbits, implantation can be delayed or inhibited by a reduction in DNA synthesis that appears to be caused by nicotine. Studies have shown a decrease in litter size in rats treated with nicotine during gestation.

Pregnancy

Pregnancy Category D (see WARNINGS)

The harmful effects of cigarette smoking on maternal and fetal health are clearly established. These include low birth weight, increased risk of spontaneous abortion, and increased perinatal mortality. The specific effects of NICODERM therapy on fetal development are unknown. Therefore pregnant smokers should be encouraged to attempt cessation using educational and behavioral interventions before using pharmacological approaches.

Spontaneous abortion during nicotine replacement therapy has been reported, as with smoking; nicotine as a contributing factor cannot be excluded.

NICODERM therapy should be used during pregnancy only if the likelihood of smoking cessation justifies the potential risk of use of nicotine replacement by the patient who may continue to smoke.

Teratogenicity

Animal Studies Nicotine was shown to produce skeletal abnormalities in the offspring of mice when given doses toxic to the dams (25 mg/kg IP or SC).

Human Studies Nicotine teratogenicity has not been studied in humans except as a component of cigarette smoke (each cigarette smoked delivers about 1 mg of nicotine). It has not been possible to conclude whether cigarette smoking is teratogenic to humans.

Other Effects

Animal Studies A nicotine bolus (up to 2 mg/kg) to pregnant rhesus monkeys caused acidosis, hypercarbia, and hypotension (fetal and maternal concentrations were about 20 times those achieved after smoking 1 cigarette in 5 minutes). Fetal breathing movements were reduced in the fetal lamb after intravenous injection of 0.25 mg/kg nicotine to the ewe (equivalent to smoking 1 cigarette every 20 seconds for 5 minutes). Uterine blood flow was reduced about 30% after infusion of 0.1 mg/kg/min nicotine for 20 minutes to pregnant rhesus monkeys (equivalent to smoking about 6 cigarettes every minute for 20 minutes).

Human Experience Cigarette smoking during pregnancy is associated with an increased risk of spontaneous abortion, low birth weight infants, and perinatal mortality. Nicotine and carbon monoxide are considered the most likely mediators of these outcomes. The effect of cigarette smoking on fetal cardiovascular parameters has been studied near term. Cigarettes increased fetal aortic blood flow and heart rate and decreased uterine blood flow and fetal breathing movements. NICODERM therapy has not been studied in pregnant humans.

Labor and Delivery

The NICODERM system is not recommended to be left on during labor and delivery. The effects of nicotine on a mother or the fetus during labor are unknown.

Use in Nursing Mothers

Caution should be exercised when NICODERM therapy is administered to nursing women. The safety of NICODERM therapy in nursing infants has not been examined. Nicotine passes freely into breast milk; the milk to plasma ratio averages 2.9. Nicotine is absorbed orally. An infant has the ability to clear nicotine by hepatic first-pass clearance, however the efficiency of removal is probably lowest at birth. The nicotine concentrations in milk can be expected to be lower with NICODERM therapy when used as directed, than with cigarette smoking, as maternal plasma nicotine concentrations are generally reduced with nicotine replacement. The risk of exposure of the infant to nicotine from NICODERM therapy should be weighed against the risks associated with the infant's exposure to nicotine from continued smoking by the mother (passive smoke exposure and contamination of breast milk with other components of tobacco smoke) and from NICODERM therapy alone or in combination with continued smoking.

Pediatric Use

NICODERM therapy is not recommended for use in children because the safety and effectiveness of NICODERM therapy in children and adolescents who smoke have not been evaluated.

Geriatric Use

Fifty-six patients over the age of 60 participated in clinical trials of NICODERM therapy. NICODERM therapy appeared to be as effective in this age group as in younger smokers. However, asthenia, various body aches, and dizziness occurred slightly more often in patients over 60 years of age.

ADVERSE REACTIONS

Assessment of adverse events in the 1,131 patients who participated in controlled clinical trials is complicated by the occurrence of GI and CNS effects of nicotine withdrawal as well as nicotine excess. The actual incidences of both are confounded by concurrent smoking by many of the patients. When reporting adverse events during the trials, the investigators did not attempt to identify the cause of the symptom.

Topical Adverse Events

The most common adverse event associated with topical nicotine is a short-lived erythema, pruritus, and/or burning at the application site, which was seen at least once in 47% of patients on the NICODERM system in the clinical trials. Local erythema after system removal was noted at least once in 14% of patients and local edema in 3%. Erythema generally resolved within 24 hours. Cutaneous hypersensitivity (contact sensitization) occurred in 2% of patients on NICODERM systems (see PRECAUTIONS, Allergic Reactions).

Probably Causally Related

The following adverse events were reported more frequently in NICODERM-treated patients than in placebo-treated patients or exhibited a dose response in clinical trials.

Digestive System Diarrhea*, dyspepsia*
Mouth/Tooth Disorders Dry mouth†
Musculoskeletal System Arthralgia*, myalgia*
Nervous System Abnormal dreams* insomnia (23%), nervousness*
Skin and Appendages Sweating*

Frequencies for 21 mg/day system
* Reported in 3% to 9% of patients
† Reported in 1% to 3% of patients
Unmarked if reported in <1% of patients

Causal Relationship UNKNOWN

Adverse events reported in NICODERM- and placebo-treated patients at about the same frequency in clinical trials are listed below. The clinical significance of the association between NICODERM systems and these events is unknown, but they are reported as alerting information for the clinician.

Body as a Whole Asthenia*, back pain*, chest pain*, pain*
Digestive System Abdominal pain†, constipation*, nausea*, vomiting†
Nervous System Dizziness*, headache (29%), paresthesia†
Respiratory System Cough increased*, pharyngitis*, sinusitis*
Skin and Appendages Rash*
Special Senses Taste perversion*
Urogenital System Dysmenorrhea*

Frequencies for 21 mg/day systems
* Reported in 3% to 9% of patients
† Reported in 1% to 3% of patients
Unmarked if reported in <1% of patients

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TX. PATIENTS: 124 children (aged 1 mo to 19 y) admitted with a diagnosis of measles. INTERVENTIONS: None. MEASUREMENTS/RESULTS: 27 patients had significant laryngotracheobronchitis, including 10 who had not received appropriate immunization. 6 patients required endotracheal intubation for relief of upper airway obstruction. The median age of patients requiring intubation was 12 mo (range, 4-24 mo). 2 patients died of complications of superinfection. 2 patients survived but required prolonged intubation. 2 patients underwent early diagnostic laryngoscopy and bronchoscopy and required shorter artificial airway maintenance. CONCLUSIONS: Severe laryngotracheobronchitis frequently occurs in patients younger than 2 years hospitalized with measles and may be related to bacterial or viral superinfection. Early diagnostic laryngoscopy and bronchoscopy for injury assessment and possible endotracheal tube exchange are recommended and, in some severe cases, tracheostomy should be considered to shorten artificial airway maintenance and decrease the incidence of airway complications.

Relationship of Oxygen Consumption and Oxygen Delivery in Surgical Patients with ARDS—PL Appel, WC Shoemaker. Chest 1992; 102:906.

Previous studies have described oxygen delivery ($\dot{D}_{O_2}$) and oxygen consumption ($\dot{V}_{O_2}$) relationships in patients with ARDS and other acute diseases that suggest occasions when $\dot{V}_{O_2}$ may be dependent on the supply of oxygen, ie, $\dot{D}_{O_2}$. We studied 127 postoperative patients who developed ARDS to evaluate the relationship of $\dot{D}_{O_2}$ to $\dot{V}_{O_2}$. We found a weak correlation between $\dot{D}_{O_2}$ and $\dot{V}_{O_2}$ in the total series ($r = 0.49$) as well as in several clinical subgroups of patients with ARDS. Moreover, we observed similar relationships in a concurrent group of 218 postoperative patients who did not develop ARDS. We also examined the $\dot{D}_{O_2}/\dot{V}_{O_2}$ data of individual patients with ARDS to identify instances where flow-dependent $\dot{V}_{O_2}$ patterns developed into flow-independent $\dot{V}_{O_2}$ patterns. We were able to identify an apparent plateau in the $\dot{D}_{O_2}/\dot{V}_{O_2}$ relationships in 29/50 (58%) patients where multiple measurements were obtained over a short period of time. Our data are consistent with the concept that the $\dot{D}_{O_2}/\dot{V}_{O_2}$ relationship in acutely ill early postoperative patients with and without ARDS is affected by antecedent circulatory problems that may lead to tissue hypoxia and tissue oxygen deficiencies that are manifest by flow dependency.

Adult Criteria for Obstructive Sleep Apnea Do Not Identify Children with Serious Obstruction—CL Rosen, L D'Andrea, GG Haddad. Am Rev Respir Dis 1992;146:1231.

Although obstructive sleep apnea (OSA) occurs in the pediatric population, diagnostic criteria have not been established. Since criteria for adult OSA are well established, we asked whether commonly used adult criteria, such as the apnea index (based on the number of obstructive apnea [OA] events per hour), would identify children with serious sleep-related upper airway obstruction. Polysomnographic data were analyzed from 20 children (ages 8 mo to 16 y) with clinical evidence of upper airway obstruction during sleep (loud snoring and labored breathing) *and* who had cyclic oscillations of oxyhemoglobin saturation (S_{aO_2}) during sleep. The overnight studies included sleep state (EEG, EOG, and EMG), S_{aO_2}, ECG, nasal (end-tidal CO_2) and oral (thermistor) airflow, chest and abdominal movement (inductance plethysmography), and video camera and behavioral observations. Measurements included the number of obstructive events ≥ 10 seconds, the number of desaturations (≥ 5% decrease lasting ≥ 5 seconds), the number of desaturation episodes to < 90%, < 85%, and < 80% lasting > 5 seconds, and the percentage of sleep time with S_{aO_2} values < 90%. Gas exchange was impaired as evidenced by cyclic decreases in S_{aO_2} and elevated P_{etCO_2} values (maximum value 58 ± 6 torr). The children experienced 175 ± 168 (range 6-609) episodes of decreased S_{aO_2} > 5%, with an average minimum S_{aO_2} of 66 ± 13% (range 30-85%). The average number of apnea events was only 1.9 ± 3.2 events/h (range 0-10.4). Of the 194 episodes of severe desaturation (defined as a decrease in S_{aO_2} > 15% for ≥ 30 seconds), only 17 (9%) occurred in association with obstructive apnea events. We conclude that (1) episodes of complete obstructive apnea are generally absent in children with serious sleep-related upper airway obstruction, (2) adult criteria for OSA based on number of OA/h will fail to identify the majority of children with serious upper airway obstruction during sleep, and (3) criteria based on the quantitative S_{aO_2}, P_{etCO_2} values, and possibly paradoxical respiratory efforts may be better indices of the presence and severity of upper airway obstruction in children.

Normal Polysomnographic Values for Children and Adolescents—CL Marcus, KJ Omlin, DJ Basinki, SL Bailey, AB Rachal, WS Von Pechmann, et al. Am Rev Respir Dis 1992;146:1235.

Although polysomnography is routinely performed to evaluate children and adolescents with sleep-disordered breathing, normal polysom-

nographic values for the pediatric age group have not yet been established. We therefore performed overnight polysomnography in 50 normal children and adolescents (mean age 9.7 ± 4.6 SD y, range 1.1-17.4 y). Of the children 56% were male. Chest-wall motion, ECG, oronasal airflow, end-tidal P_{CO_2} (P_{etCO_2}), arterial oxygen saturation (S_{aO_2}), and electro-oculogram were monitored. Children had 0.1 ± 0.5 (range 0-3.1) obstructive apneas per hour of total sleep time, with only 18% of children having any obstructive apneas. No child had obstructive apneas > 10 seconds in duration. Of the children, 30% had central apneas ≥ 10 seconds in duration, and one child had a central apnea associated with S_{aO_2} < 90%. Peak P_{etCO_2} was 46 ± 4 torr (range 38-53 torr), and hypoventilation (P_{etCO_2} > 45 torr) occurred for 7 ± 19% total sleep time (range 0-91%). The S_{aO_2} nadir was 96 ± 2% (range 89-98%), with only one child desaturating below 90% in association with a central apnea. We conclude that polysomnographic results in the pediatric age group differ from those in adults. Recommendations for normal polysomnographic criteria are given.

Effects of the Implementation of a Smoke-Free Policy in a Medical Center—KP Offord, RD Hurt, KG Berge, DK Frusti, L Schmidt. Chest 1992;102:1531.

The implementation of a smoke-free policy in this medical center was associated with a decrease in the prevalence of regular cigarette smoking from 16.7% to 13.8% and a smoking cessation rate of 22.5% among regular smokers over the 2.5 years since the policy was announced. This decrease in prevalence is the result of both smoking cessation among existing employees and less frequent regular smoking among new employees. At 2-year follow-up, the policy was overwhelmingly endorsed by medical center staff overall but was viewed less favorably by those who continued to smoke. Nevertheless, over the 2.5 years, many of these smokers have been in the action stage of cessation (37.1% made a serious attempt to stop smoking, 20.7% had used nicotine polacrilex in a smoking-cessation effort, and 13.8% had attended a formal cessation program). The implementation of a smoke-free policy has made a significant contribution toward providing a healthful work environment and toward encouraging nonsmoking behavior in staff and patients.

A Comparison of Three Pulmonary Artery Oximetry Catheters in Intensive Care Unit Patients—PE Scuderi, DL Bowton, JW Meredith, LC Harris, J Evans, RL Anderson. Chest 1992;102:896.

OBJECTIVE: To compare the clinical performance of 3 pulmonary artery oximetry catheters (Oximetrix 3, SAT-2, and $HEMOPRO_2$) in intensive care unit (ICU) patients. DESIGN: Unblinded comparison of performance over 24 h using an IL-282 CO-oximeter as a criterion standard. SETTING: Multispecialty adult ICU at a university teaching hospital. PATIENTS: 30 critically ill patients selected from those requiring hemodynamic monitoring for medical management. MEASUREMENTS & MAIN RESULTS: By all measures, performance of the Oximetrix 3 and SAT-2 systems were comparable; bias ± precision were −1.98 ± 3.07 and +1.80 ± 3.49, respectively, vs −2.28 ± 5.24 for the $HEMOPRO_2$. The Oximetrix 3 and SAT-2 systems demonstrated consistent performance over the range of saturations tested, though Oximetrix 3 tended to underestimate and SAT-2 tended to overestimate the CO-oximeter value. The $HEMOPRO_2$ underestimated the CO-oximetry-derived saturation, although this was not constant across the range of values tested. The 95% confidence limits based on intrasubject variability were similar (±4.59, ±5.66, and ±6.56 for the Oximetrix 3, SAT-2, and $HEMOPRO_2$, respectively); however, the 95% confidence limits based on total variability, while similar for Oximetrix 3 (±6.03) and SAT-2 (±6.86), were larger for the $HEMOPRO_2$ (±10.30). The expected SD was similar for the three systems (2.03, 2.50, and 2.90 for the Oximetrix 3, SAT-2, and $HEMOPRO_2$ systems, respectively). None of the systems equaled or exceeded ($p > 0.05$) the manufacturers' published specifications, which, in all cases, are listed as ±2% (saturation; 1 SD) when compared with bench oximetry. CONCLUSIONS: Although each system measures mixed venous oxygen saturation, the Oximetrix 3 and SAT-2 systems demonstrate closer agreement with CO-oximetry. However, none of these catheters provided statistically significant evidence that they would perform within ±2% of CO-oximetry. As a continuous monitor used to detect changes or trends, any of the three may be acceptable.

Evaluation of a Reservoir Device for Metered-Dose Bronchodilator Delivery to Intubated Adults: An In Vitro Study—JL Rau, RJ Harwood, JL Groff. Chest 1992;102:924.

We investigated the use of a reservoir device for delivery of a MDI bronchodilator aerosol using a lung model of an intubated, mechanically ventilated adult. METHODS: Albuterol (Proventil) was delivered with a MDI using three methods. In Method 1, the MDI was attached directly onto the ETT using a commercially available actutator/adapter. In Meth-

od 2, the Monaghan AeroVent reservoir was placed on the inspiratory limb of the ventilator circuit just before the patient Y connector. In Method 3, the AeroVent was placed between the patient Y connector and the ETT. Standardized ventilator settings with a Servo 900C were used for all three methods ($\dot{V}_E$ = 9.6 L; respiratory rate = 12 breaths/min; t_i = 20% or 1 s). Aerosol drug delivery was measured at the distal tip of the ETT using a spectrophotometric technique. Percentage of amount delivered was calculated from measured delivery of the MDI. RESULTS: The MDI directly on the ETT delivered 7.3% of the total dose to the end of the ETT. The AeroVent on the inspiratory limb increased this to 32.1% and the AeroVent between the Y connector and the ETT delivered 29%. Both reservoir delivery methods delivered significantly more drug than direct placement of the MDI on the ETT ($p < 0.01$) but did not differ from each other ($p > 0.05$). CONCLUSION: Use of the AeroVent reservoir chamber significantly increased bronchodilator delivery by aerosol with a MDI in an adult lung model of an intubated patient on ventilatory support.

Nasal Mask Ventilation in Acute Respiratory Failure: Experience in Elderly Patients—D Benhamou, C Girault, C Faure, F Portier, J-F Muir. Chest 1992;102:912.

Nasal mask ventilation (NMV) has been used successfully in chronic restrictive respiratory failure and more recently in acute exacerbations of chronic obstructive pulmonary disease (COPD). This study aimed to evaluate the possible role of NMV in acute respiratory failure (ARF) episodes when mechanical ventilation with endotracheal intubation is questionable. Thirty patients (age 76 ± 8.1 y) were treated by NMV during ARF episodes (COPD, 20; other chronic respiratory failure [CRF], 5; chronic heart failure [CHF], 4). All patients were hypoxemic (P_{aO_2}, 5.85 ± 1.62 kPa) and hypercapnic (P_{aCO_2} 8.63 ± 1.89 kPa) with respiratory acidosis (pH, 7.29 ± 0.08). In all cases, clinical or physiologic parameters indicated the need for mechanical ventilation, but endotracheal intubation was either not applied because of the age and the physiologic condition of the patients (17 cases) or was postponed (13 cases). NMV was performed using a volume-cycled ventilator and a customized nasal mask. Ventilation was continuous during the first 12 hours and the following nights and was then intermittent during the day. 21 patients improved clinically, within a few hours. Progressive correction of arterial blood gases was observed: P_{aO_2} increased during the first hour, but P_{aCO_2} decreased more slowly. 18 patients were able to be successfully weaned from NMV. 12 patients failed to improve despite NMV: 8 of them died and 4 required endotracheal intubation. There was no difference in the success rate between patients in whom endotracheal ventilation was contraindicated or postponed. Clinical tolerance was satisfactory in 23 patients and poor in 7 patients. A return to the respiratory condition was observed in the surviving patients with subsequent discharge from hospital. NMV therefore successfully treated respiratory distress initially in 60% of the 30 patients. These results suggest that NMV could be a possible alternative in the treatment of ARF, even in very ill patients, when endotracheal ventilation is controversial or not immediately required.

Accuracy of Capnography in Nonintubated Surgical Patients—S-Y Liu, T-S Lee, F Bongard. Chest 1992;102:1512.

Previous studies have reported mixed results when correlating $ETCO_2$ and P_{aCO_2} in mechanically ventilated patients with underlying respiratory disease. However, the utility and accuracy of capnography in nonintubated patients, without chronic pulmonary disease, has received little attention. We studied 25 nonintubated surgical patients to (1) examine the correlation between P_{aCO_2} and $ETCO_2$ and (2) describe the relationship between dead space (V_D/V_T), venous admixture, and $P_{(a\text{-}et)CO_2}$. End tidal CO_2 was lower than P_{aCO_2} by an average of 3.6 torr. Regression analysis found a close correlation between dead space and the $P_{(a\text{-}et)CO_2}$ gradient ($r = 0.77$, $p < 0.001$), while venous admixture was of lesser importance ($r = 0.47$). Capnographic estimates of P_{aCO_2} can be useful for continuously monitoring the respiratory status of nonintubated spontaneously breathing patients weaned from mechanical ventilation. This may be of particular value in trauma victims and in selected surgical patients without underlying respiratory disease in whom other injuries require continued critical care.

Pulse Oximetry in the Postoperative Care of Cardiac Surgical Patients: A Randomized Controlled Trial—MI Bierman, KL Stein, JV Snyder. Chest 1992;102:1367.

STUDY OBJECTIVE: To demonstrate the utility of pulse oximetry in detecting clinically unapparent episodes of arterial desaturation in postoperative cardiac surgical patients and to evaluate the effect of pulse oximetry on ordering arterial blood gas analyses. DESIGN: Prospective, randomized, partially blinded comparison. SETTING: Cardiothoracic surgical intensive care unit. PATIENTS: 35 patients following elective cardiac surgical procedures. INTERVENTIONS: All patients were monitored continuously with pulse oximetry throughout their ICU course. In Group 1 patients, the S_{pO_2} data were available at the bedside. In

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Group 2 patients, the S_{pO_2} data were masked at the bedside and monitored at a remote location. MEASUREMENTS & RESULTS: Utilization of pulse oximetry allowed a significant reduction in arterial blood gas utilization in Group 1 (Group 1: 12.4 ± 7.5 blood gas analyses per ICU admission vs Group 2: 23.1 ± 8.8; p = 0.0007) without adverse events. Clinically unapparent desaturations were detected in 7 of 15 patients in Group 2. CONCLUSIONS: Pulse oximetry improves patient safety through the detection of clinically unapparent episodes of desaturation and can allow a reduction in the number of blood gas analyses utilized without adverse effects to the patient. This may allow a potential cost savings to the patient.

Inpatient Management of Status Asthmaticus—A Spevetz, T Bartter, J Dubois, MR Pratter. Chest 1992; 102:1392.

We examined physician management of patients hospitalized for status asthmaticus at a university hospital. A retrospective review of consecutive admissions for status asthmaticus covering a 13-month period yielded 130 charts for review. We found that practice patterns with respect to documentation of severity of illness, medications, and documentation of efficacy of therapy fell short of the current state of knowledge with respect to treatment of asthma. Asthma is a treatable disease, and physician education needs to bridge the gap between current practice patterns and standards of optimal therapy as defined in the literature.

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Misallocation of Respiratory Care Services: Time for a Change

In the current health care environment that demands both proficient and efficient care, a guiding principle is to provide the right care to patients who need care and for whom the care is likely to be effective. When we stray from this rule, we incur the risk of misallocating care in two ways: First, we misallocate care when we provide unneeded care (ie, no indication for treatment exists or though an indication exists, the care provided is unlikely to help) and, second, we misallocate care when we fail to provide therapy that is needed, presuming that the treatment has efficacy.

In order to continue to thrive, respiratory care must meet the challenges of proficiency and efficiency and must recognize and overcome the impediments that threaten these goals. What are these impediments? How are we responding now and what future needs exist? The purpose of this editorial is to consider these questions and to offer the concept of therapist-driven protocols,[1,2] alternately known as a Respiratory Therapy Consult Service,[3] as a promising solution.

One obvious need in respiratory care is to examine critically the efficacy of respiratory care treatments and to provide only those treatments for which a valid scientific basis exists. The rise and subsequent fall of blow bottles and earlier overzealous use of intermittent positive pressure breathing (IPPB) are stinging examples of misdirected but popular treatments that underscore the need to examine our practices critically. Herein lies the value of the Clinical Practice Guidelines,[4,5] whose purpose is to articulate the scientific basis for commonly used respiratory care treatments in order to "improve the appropriateness of respiratory care practices throughout the country."[6] In instances where current practice outstrips available scientific support and where controversy exists, the Clinical Practice Guidelines should encourage uniformity of practice and facilitate much-needed outcomes research.

Another major need is to avoid misallocating respiratory care, by neither providing too much nor too little respiratory therapy. To do this, it is necessary to seek and identify misallocation and to ascertain by how much, with which treatments, and to which patients. The peer-reviewed literature provides some guidance about where and how much misallocation is taking place today. Much of the available evidence documents overuse of respiratory care services,[7-14] but some literature also suggests underuse.[15] One example of overuse of respiratory care services has been reported by Zibrak et al.[10] After implementing appropriateness criteria for respiratory care services, use of aerosol medication declined by 58%, IPPB declined by 92%, and incentive spirometry declined by 55%, all without demonstrable adverse effects on the outcome measures considered (ie, mortality, some pulmonary complications reviewed retrospectively, patient length of stay). Another example of overuse of respiratory care services is the observation by Browning et al that 42.7% of arterial blood gases ordered in a surgical ICU failed to satisfy appropriateness criteria.[12] Gratifyingly, implementation of guidelines caused the frequency of inappropriate arterial blood gases to fall to 32.9% acutely and to remain lower at 30.8% several months later. Notably, when the source of inappropriate ABG orders was examined in this study, the rate of inappropriate ordering was far lower among respiratory therapists (3-15%) than among others (37-45%). In another example of overuse, Brougher et al[11] reported that 38% of oxygen orders failed to meet either clinical or physiologic indications and more re-

cently, Small et al[13] reported that 23% of orders for oxygen in hospital inpatients were for use on an "as needed" basis and that ordering and implementing oxygen appeared more cavalier than ordering antibiotics in the same institution. In another audit, Lowe[7] recently reported that 26% of pediatric respiratory care orders were deemed inappropriate. Finally, in our own institution, Kester and Stoller[3] reported that 25.2% of respiratory care orders initiated for 230 non-ICU adult inpatients were deemed unlikely to provide clinical benefit, even when lenient appropriateness criteria were applied. Overall, across the spectrum of treatment types, patients, and hospital settings, the frequency of overusing respiratory care services seems to cluster between 20% and 40%.

On the other side of misallocation, what evidence suggests that we also fail to provide services when respiratory care might help? On the one hand, observations like those of Zibrak et al[10] that eliminating some respiratory care services was unassociated with adverse effects could be interpreted to suggest that overuse exceeds underuse. However, confidence in such a conclusion from this study requires considering outcomes other than mortality or length of stay alone. Specifically, were preventable re-admissions to the ICU for respiratory distress avoided? Were respiratory urgencies avoided? (eg, severe bronchospasm and atelectasis requiring bronchoscopy) To the extent that such events were not recorded in this study, the rate of underordering respiratory care may be underestimated.

More direct evidence for underuse of respiratory care services comes from our own observations at the Cleveland Clinic. In the same retrospective review in which 25.2% of orders were deemed inappropriate, 11.2% of patients were deemed fitting candidates for respiratory care that was not ordered for them.[3] Furthermore, this 11.2% may underestimate the true rate of underordering, because the study sample frame was 230 adult inpatients for whom some type of respiratory care was prescribed. This sample excludes the larger universe of patients for whom no respiratory care was ordered, but for whom a need for effective respiratory care may exist. Clearly, more information about both over- and underuse of respiratory care services is needed, but available data and experience suggest that misallocation is widespread.

Correcting misallocation requires knowing its cause, knowing who is responsible for overordering and underordering, and knowing how to modify these practices in order to re-align the need for respiratory care with the provision of respiratory care services.

In a traditional care system where physicians order respiratory care services, misallocation occurs when physicians over- and/or underorder respiratory therapy. Personal observation and my own training experience suggest two explanations for "mis-ordering" respiratory care: (1) Little attention is given to teaching principles of respiratory care in traditional medical school curricula or in postgraduate training, and (2) Physicians' uncertainty about the indications for respiratory therapy reflects remaining scientific uncertainty about specific indications for some respiratory therapies.

What solutions can be suggested? To the extent that misallocation results from a lack of scientific or clinical certainty, more research is needed. The Clinical Practice Guidelines[4,5] and enthusiasm for further efficacy studies about respiratory care should help. To address the educational shortcomings of medical trainees and practitioners, more attention to teaching and to instilling enthusiasm for learning respiratory care is needed, both in medical schools and thereafter.

A more promising strategy to reduce misallocation of respiratory care is to reorganize the way respiratory care is ordered. One novel strategy to deliver respiratory care is to impart responsibility for allocating respiratory care services to practitioners with the greatest expertise. Indeed, several examples of such innovative respiratory care delivery programs have been implemented already and go by the following names (depending on the scope and purpose of the program): therapist-driven protocols, respiratory care protocols, evaluate-and-treat programs, and a Respiratory Therapy Consult Service. Let us consider some examples of existing programs and their impact. To avoid overuse of bronchial hygiene therapy (BHT) at Northwestern Medical Center, Shapiro et al[8] implemented a system in which respiratory care practitioners determined BHT for non-ICU adult inpatients. Historical comparison of services given before the bronchial hygiene therapy program showed that the new program (under authoritative medical direc-

tion) was associated with a 61% decrease in BHT and $250,000 savings without an increased average length of stay or identifiable morbidity attributable to deficient BHT. Furthermore, that fewer physicians requested unneeded services suggests that the program improved physicians' ordering practices. Other protocol-based programs in which respiratory care practitioners allocate care have been reported for providing perioperative respiratory therapy,[1,14,16] for medicated aerosol therapy and lung-hyperinflation therapy,[14,17] for ordering arterial blood gases,[12] for intubating the airway,[18] for training with metered dose inhalers,[17,19] for weaning from mechanical ventilation,[20] and, in the longest-standing program at Lutheran Medical Center in Wheat Ridge, Colorado, for all inpatient respiratory care services.[1,2] More recently implemented examples of comprehensive protocol-based programs include the Respiratory Care Plan at the Fox Chase Cancer Center[9] and the Respiratory Therapy Consult Service at the Cleveland Clinic Foundation,[21] both of which use sign- and/or symptom-based algorithms to specify respiratory care plans for adult inpatients.

Experience with respiratory care protocol programs has been very encouraging to date. Most have been well accepted and have been associated with a reduction in services examined without identifiable adverse affects.[1,10] Still, most respiratory care protocol services are in their infancy, and because available evaluations of their impact have shortcomings or are preliminary, more extensive, critical evaluation of their impact is clearly needed. As an example of the shortcomings of available studies, current estimates of the decreased utilization of respiratory care services associated with protocol-based programs are based on historical comparisons.[10] To avoid biases related to changing practice patterns over time, comparison between protocol-based respiratory care and 'traditional' (ie, physician-determined) ordering practices should use concurrent control groups. Furthermore, to assure that differences in respiratory care orders, length of stay, or care charges are attributable to the protocol-based care rather than to differences in patients' underlying diseases or acuteness of condition, future studies should assure that the compared groups have similar needs for respiratory care services. As a specific example of this need, our preliminary concurrent comparison of the Cleveland Clinic Respiratory Therapy Consult Service to traditional ordering practices[21] suggests that physicians seek respiratory care consultation for sicker patients, avoiding consults in patients with milder respiratory illness. While this is by no means surprising when the program can be ordered at the physician's discretion, this observation emphasizes that to assure fair comparison, studies must stratify patients' risks for study outcome events. To maximally defend against susceptibility bias,[22] a randomized clinical trial of protocol-based respiratory care ordering versus traditional care should be undertaken.

In summary, with increasing scrutiny given to the effectiveness and costs of health care, innovative programs that allocate respiratory care ordering to practitioners based on rigorous, specified appropriateness criteria and/or branching-logic algorithms are a promising solution to respiratory care misallocation. Widespread acceptance and implementation will require staunch medical directors' input and advocacy, therapists' support for new programs and for leaving the comforts of 'traditional' practice, and confirmation of the benefits of Respiratory Therapy Consult Services by more extensive, 'hard-nosed' evaluation.

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Tracheostomy Discontinuation: Impact of Tube Selection on Resistance during Tube Occlusion

Barry Beard BA RRT and Frank J Monaco BA RRT

During tracheostomy discontinuance trials when tracheostomy tubes are occluded, it may be expected that the transition from tracheostomy to laryngeal ventilation will be accompanied by an increase in airways resistance (R_{aw}) caused by the presence of the tracheostomy tube in the trachea. Because successful decannulation may be affected by this added resistance, we studied the extent to which various tracheostomy tube configurations contribute to R_{aw}. R_{aw} was determined using model tracheas with three types of tracheostomy tubes in place and at varying gas flowrates. R_{aw} was least for uncuffed fenestrated tubes (0.33 cm $H_2O \cdot s \cdot L^{-1}$ [0.03 kPa $\cdot s \cdot L^{-1}$] at 0.33 L/s) and greatest for cuffed fenestrated tubes with the cuff inflated (1.61 cm $H_2O \cdot s \cdot L^{-1}$ [0.16 kPa $\cdot s \cdot L^{-1}$] at 0.33 L/s). With the cuff deflated, R_{aw} was less than 0.79 cm $H_2O \cdot s \cdot L^{-1}$ [0.08 kPa $\cdot s \cdot L^{-1}$] at 0.33 L/s but still significantly greater ($p < 0.05$) than with the uncuffed tubes. These results suggest that when tracheostomy tubes are occluded during the process of tracheostomy decannulation, the presence of a cuff, whether inflated or deflated, can increase the amount of ventilatory work required of the patient (ie, R_{aw} is one of the variables affecting the work of breathing) and that uncuffed tubes should be expected to increase the likelihood of success and improve patient comfort during the process of tracheostomy decannulation. (Respir Care 1993;38:267-270.)

Introduction

Many patients who require tracheostomy during the management of an acute illness do recover to the extent that the tracheostomy tube can be removed and the stoma allowed to heal. However, because the presence of a tracheostomy tube can adversely affect laryngeal function,[1] the decision to decannulate generally follows a trial period during which the patient becomes reacquainted with natural breathing, via the larynx.[2] Restoring laryngeal participation in ventilation with a tracheostomy tube still in place can be accomplished by the use of a fenestrated tube (with or without a cuff) or by gradually reducing tube size.[2] Reducing the size of the tracheostomy tube would seem to be the most direct manner of reducing intratracheal resistance to airflow. However, it has been the practice in our institution (until recently) to begin tracheostomy weaning by replacing the existing non-fenestrated tube with a cuffed fenestrated tube of the same size because (1) we wanted a cuff in the event that aspiration was a problem or we had to ventilate the patient, and (2) we did not want to compromise the size of the stoma until patient success was more assured.

While participating in tracheostomy decannulations, we had observed that some patients appear to be obstructed when the tracheostomy tube is occluded despite the fact that we had just made it easier for them by placing a fenestrated tube, and some patients who had not tolerated the occlusion of a cuffed fenestrated tube (even with the cuff deflated), would tolerate a uncuffed tube (even with-

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out a fenestration). We had also observed that many times the fenestration of the tube would not align within the patient's trachea. The presence of any one of these conditions might lead to a failed occlusion trial. We designed a bench test to quantitate the resistance to tracheal airflow offered by different types of occluded tracheostomy tubes.

Methods and Materials

We measured the resistance (R_{aw}) offered by (1) a cuffed fenestrated tube with cuff inflated, (2) a cuffed fenestrated tube with cuff deflated, (3) an uncuffed fenestrated tracheostomy tube (all Shiley)* and (4) a Jackson-type metal tube with neither cuff nor fenestration, by ventilating model tracheas with the occluded tracheostomy tubes in place. All tubes used were size 8 because the purpose of the study was to determine differences between types of tubes, not sizes of tubes. Those specific tubes were selected for study because they were the types being purchased by Penrose Hospital. We constructed models using 3/4-inch (1.9-cm) ID smooth-bore tubing 15 cm in length and the 3 types of tracheostomy tubes (Fig. 1). We positioned tubes optimally within the model tracheas so that fenestrations were not obstructed. Ports attached at both the proximal (laryngeal) and distal (tracheal) end of the model provided for sampling the intratracheal pressure gradient. We then attached the models to a Timeter RT-200 Calibration Analyzer (Fig. 2), calibrated according to the manufacturer's recommendations. Flow was introduced via the RT-200 into the laryngeal end of the model with an Ohio Medical Products air flowmeter. Gas flowrate was monitored with the RT-200, and when the desired flow was attained, airway pressures were measured both proximal and distal to the occluded tracheostomy tube. (Accuracy of the RT-200 is reported by the manufacturer to be ±1% of reading for pressure and ±2% of reading for flow.) The gas flowrates introduced ranged from 0.33 L/s (to approximate 'normal' ventilation) to 1.5 L/s (to approximate a worst-case scenario of high minute ventilation in the presence of obstructive airways disease). We ran three separate trials for each configuration at each gas flowrate. R_{aw} was calculated as the difference in proximal and distal airway pressures/liter flow. ANOVA was to be used to determine the significance of any observed differences.

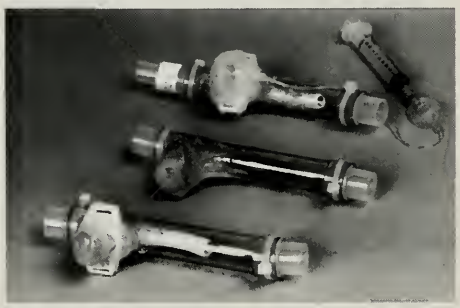

Fig. 1. Model tracheas with occluded tracheostomy tubes in place.

Fig. 2. Model trachea connected to the RT-200 calibration analyzer.

Results

Results for a given tube configuration did not vary during any of the three separate trials. R_{aw} was least for the uncuffed fenestrated tube and greatest for the cuffed fenestrated tube with the cuff inflated (Table 1). ANOVA revealed the differences to be statistically significant at $p < 0.05$. For the cuffed fenestrated tube with the cuff inflated, R_{aw} increased over fourfold as gas flow was increased from 0.33 L/s to 1.5 L/s, whereas R_{aw} remained less than 1 cm $H_2O \cdot s \cdot L^{-1}$ [0.06 kPa $\cdot s \cdot L^{-1}$] as flow introduced into the uncuffed fenestrated mod-

*Suppliers are identified in the Product Sources section at the end of the text.

Table 1. Airways Resistance during Tracheostomy Tube Occlusion

Tube Type*	Inspiratory Gas Flow (L/s)				
	0.33	0.67	1.00	1.33	1.50
	Resistance cm $H_2O \cdot s \cdot L^{-1}$ [kPa $\cdot$ s $\cdot$ L^{-1}]				
Cuffed fenestrated; cuff inflated	1.61 [0.16]*	3.01 [0.30]	4.50 [0.44]	5.97 [0.59]	6.83 [0.67]
Cuffed fenestrated; cuff deflated	0.79 [0.08]	1.37 [0.13]	1.94 [0.19]	2.47 [0.24]	2.78 [0.27]
Non-cuffed fenestrated	0.33 [0.03]	0.48 [0.05]	0.63 [0.06]	0.77 [0.08]	0.86 [0.08]
Jackson	0.45 [0.04]	0.73 [0.07]	0.96 [0.09]	1.17 [0.11]	1.28 [0.13]

*All tubes were size 8.

el was increased to 1.5 L/s. R_{aw} for the Jackson tube was quite similar to that for the uncuffed fenestrated tube (Fig. 3).

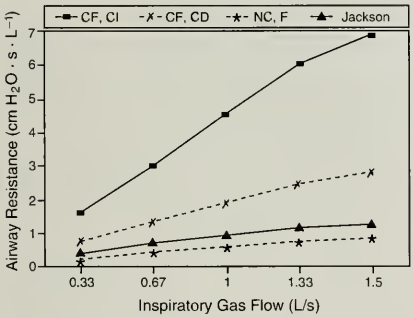

Fig. 3. Graphic analysis of R_{aw} during tracheostomy tube occlusion. CF, CI: cuffed fenestrated, cuff inflated; CF, CD: cuffed fenestrated, cuff deflated. NC, F: uncuffed fenestrated.

Discussion

Normal values for R_{aw} may be expected to range from 0.6 to 4.0 cm $H_2O \cdot s \cdot L^{-1}$ [0.06 to 0.39 kPa $\cdot$ s $\cdot$ L^{-1}] (measured at flowrates of 0.5 L/s).[3,4] In the presence of obstructive pulmonary disorders, R_{aw} may increase to as much as 15.0 to 18.0 cm $H_2O \cdot s \cdot L^{-1}$ [1.47 to 1.77 kPa $\cdot$ s $\cdot$ L^{-1}].[4] Our data suggest that the presence of an occluded tracheostomy tube can add an appreciable amount of resistance depending upon the specific configuration (ie, tube type, cuff inflated or deflated) and ventilatory pattern (ie, inspiratory flowrate). During resting ventilation in individuals without obstructive pulmonary disorders, the presence of an occluded tracheostomy tube may not greatly increase the work of breathing. However, in the presence of obstructive pulmonary disorders in which prolonged expiratory times are associated with higher inspiratory flowrates, particularly prior to a cough maneuver or when minute ventilation is otherwise increased, R_{aw} may be increased substantially during tracheostomy tube occlusion.

We emphasize that the results reported here are for tubes that fit properly within the tracheal lumen as opposed to the not uncommon clinical finding of tracheal tube fenestra partially occluded by tissue as a consequence of poor fit—a condition characterized by even higher resistance.

Fenestrated tracheostomy tubes, by virtue of their ability to maximize tracheal airflow with the tracheostomy tube in place, would seem ideally suited to the task of acclimating the patient to laryngeal ventilation. Unfortunately, the standard fenestra of mass-produced tubes may be adequate for only a small percentage of patients,[5] and serious upper airway obstruction has been reported to accompany tracheostomy tube occlusion in the presence of improperly positioned fenestra.[6] Furthermore, while custom fenestrated tubes can be ordered[7] or manufactured at the bedside,[5,8] the fe-

nestra itself may cause the formation of granulomatous tissue[9] and compromise the achievement of tracheostomy discontinuance.

The amount of resistance to tracheal airflow imposed by occluded tracheostomy tubes varies substantially among the types of tracheostomy tube configurations tested. Tracheostomy tube selection, therefore, seems an important component of tracheostomy decannulation plans. Uncuffed tracheostomy tubes appear to offer the least increase in resistance and probably should be preferentially employed during tracheostomy occlusion. This should minimize patient work of breathing and failures due to unnecessarily high resistance during occlusion resulting from tube-created airway obstruction. Additionally, problems accompanying the use of fenestrated tubes might be avoided by using a Jackson tube, which we found to have R_{aw} levels comparable to the uncuffed fenestrated tube. Investigation of other brands of fenestrated tracheostomy tubes is warranted because the resistance imposed by them may vary from those we observed.

ACKNOWLEDGMENTS

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PRODUCT SOURCES

Tracheostomy Tubes:

Jackson-type tracheostomy tube, Baxter Healthcare Corp, Overland Park KS

Uncuffed fenestrated tracheostomy tube, Shiley Inc, Irvine CA

Cuffed fenestrated tracheostomy tube, Shiley Inc, Irvine CA

Flowmeter:

Air flowmeter, Ohio Medical Products, Madison WI

Calibration Analyzer:

Timeter RT-200, Allied Healthcare Products, St Louis MO

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An Evaluation of the Effects of Fatigue, Impedance, and Use of Two Hands on Volumes Delivered during Bag-Valve Ventilation

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PURPOSE: We conducted this study to evaluate the effects of fatigue, impedance (resistance and compliance), and use of 2 hands on the volumes delivered during manual bag-valve ventilation. METHODS & MATERIALS: Ventilation was delivered to a Michigan Instruments Test Lung. An adult Laerdal resuscitator with gas collection head was used with a Bear VM-90 to measure tidal volumes. All participants (n = 14) were familiar with bag-valve ventilation. Each person ventilated the test lung for 30 minutes. Each tidal volume was recorded for Minutes 2, 15, and 30. Grip strength was measured using a mechanical digital grip-strength tester for both the dominant and nondominant hands before and after each 30-minute trial. Each subject participated four times: using 1 hand and 2 hands with low impedance (compliance of 50 mL/cm H_2O, resistance of 5 cm $H_2O \cdot s \cdot L^{-1}$) and high impedance (compliance of 20 mL/cm H_2O, resistance of 20 cm $H_2O \cdot s \cdot L^{-1}$). The order of testing was randomly determined and a minimum 30-minute recovery time was allowed between test periods. RESULTS: There was no significant difference in V_T for the three measurement periods ($p = 0.16$). There was a significant difference in V_T for the impedance levels ($p = 0.002$) and for 1 hand versus 2 hands ($p < 0.001$). During one-hand ventilation, there was a small but significant decrease in grip strength for the dominant hand ($p = 0.02$), but no change in grip strength for the nondominant hand ($p = 0.73$). CONCLUSIONS: The effects of lung impedance and using 2 hands for manual bag-valve ventilation were greater than the effect of fatigue on tidal volume delivery during use of manual bag-valve resuscitators. (Respir Care 1993;38:271-275.)

Introduction

Manual bag-valve resuscitators are commonly used during cardiopulmonary resuscitation. They are also used during the transport of apneic patients and during endotracheal suctioning. Various aspects of the performance of bag-valve resuscitators have been published in the past 10 years. The effects of impedance[1,2] and use of two hands[2-6] on volumes delivered during manual bag-valve ventilation have been previously studied. To our knowledge, the effects of fatigue during bag-valve ventilation have not been reported. During resuscitation, and more frequently during patient transport, manual bag-valve resuscitators may be used for extended periods of time. The purpose of this study was to evaluate the effects of fatigue, impedance (resistance and compliance), and use of two hands on the volumes delivered during manual bag-valve ventilation.

Methods and Materials

We recruited 14 persons to participate in the study. All were certified in Basic Cardiac Life Sup-

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A version of this paper was presented by Mr Simmons during the RESPIRATORY CARE OPEN FORUM at the 1992 AARC Annual Meeting held in San Antonio, Texas.

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port, and all were familiar with the technique of manual bag-valve ventilation. Each subject was instructed to ventilate a Michigan Instruments Training Test Lung for 30 minutes as he/she would ventilate a patient, using a rate of about 12-15 breaths/min. A Laerdal adult bag-valve resuscitator with gas collection head was used. A Bear VM-90 ventilation monitor[7] was attached to the gas collection head of the resuscitator to allow 'exhaled' volumes from the test lung to be measured. The accuracy of the ventilation monitor was determined by use of a 1.0-L calibration syringe. The test setup was similar to that used in other published studies that have evaluated volume delivery during manual bag-valve ventilation.[2,4,5]

Each subject participated in the study four times using four sets of conditions: using 1 hand or 2 hands with low impedance (compliance of 50 mL/cm H_2O and resistance of 5 cm $H_2O \cdot s \cdot L^{-1}$) or high impedance (compliance of 20 mL/cm H_2O and resistance of 20 cm $H_2O \cdot s \cdot L^{-1}$). The order of testing was randomly determined, and a minimum 30-minute recovery time was allowed between test periods. Each tidal volume was recorded for Minutes 2, 15, and 30. For one-hand ventilation, the subjects were instructed to use their dominant hands. The nondominant hand was not used during one-hand ventilation. Grip strength was measured using a mechanical digital grip-strength tester for both hands before and after each 30-minute trial. All evaluations were conducted at usual room temperature.

Mean and standard deviation were determined for tidal volume and respiratory rate at Minutes 2, 15, and 30. Coefficient of variation was determined for tidal volume by dividing the standard deviation by the mean. Three-way analysis of variance was conducted with impedance (two levels), time (three levels), and one hand versus two hands (two levels) as repeated measures factors. The dependent variables assessed were tidal volume and coefficient of variation. $p \leq 0.05$ was considered significant. All statistical analysis was determined using commercially available statistical analysis software and standard statistical methodology.[8]

Results

The results are summarized in Tables 1 and 2 and in Figure 1. All subjects were able to complete each 30-minute trial. The respiratory rates remained fairly constant for each evaluation period (Table 1).

Table 1. Summary of Results for Tidal Volume and Coefficient of Variation during Bag-Valve Ventilation

	Minute 2	Minute 15	Minute 30
Respiratory rate (breaths/min)			
High impedance; one hand	13 (3)*	13 (4)	13 (4)
Low impedance; one hand	15 (4)	13 (4)	14 (4)
High impedance; two hands	13 (2)	13 (3)	13 (3)
Low impedance; two hands	12 (3)	12 (3)	13 (3)
Tidal volume (L)			
High impedance; one hand	0.59 (0.08)	0.59 (0.07)	0.58 (0.06)
Low impedance; one hand	0.73 (0.12)	0.72 (0.15)	0.73 (0.14)
High impedance; two hands	0.84 (0.18)	0.90 (0.19)	0.86 (0.20)
Low impedance; two hands	0.99 (0.20)	1.00 (0.19)	0.96 (0.17)
Coefficient of variation for tidal volume (%)			
High impedance; one hand	4.1 (1.6)	4.5 (1.6)	5.0 (1.9)
Low impedance; one hand	4.4 (1.4)	5.3 (2.1)	5.7 (2.3)
High impedance; two hands	4.4 (1.5)	4.8 (1.8)	5.6 (2.2)
Low impedance; two hands	4.7 (3.4)	4.3 (2.0)	4.9 (1.7)

*Values are mean (SD).

There was no significant difference in tidal volume at Minutes 2, 15, and 30 ($p = 0.16$). There was, however, a significant difference in tidal volume for

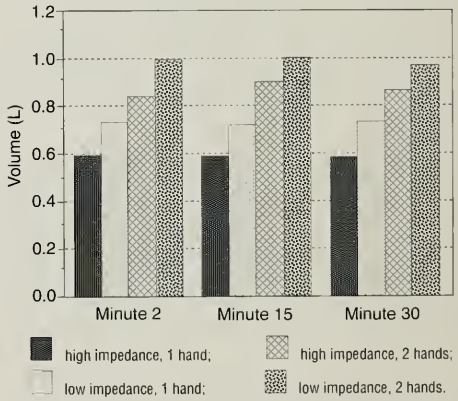

Fig. 1. Tidal volumes delivered at Minutes 2, 15, and 30 with high and low impedance, and using one and two hands to squeeze the bag.

the two levels of impedance ($p = 0.002$) and for one hand versus two hands squeezing the bag ($p < 0.001$). There were no significant interaction effects for the dependent variable tidal volume.

There was a small but significant decrease in the grip strength of the dominant hand following 30 minutes of one-hand ventilation ($p = 0.02$, Table 2). There were no significant differences in grip strength of the dominant hand for levels of impedance ($p = 0.99$) or number of hands used to squeeze the resuscitator ($p = 0.99$). There were no significant differences in grip strength for the nondominant hand for time ($p = 0.73$), impedance level ($p = 0.83$), or number of hands used to squeeze the resuscitator ($p = 0.80$). There were no significant interaction effects for the dependent variable grip strength.

Table 2. Summary of Results for Grip Strength

	Beginning	End
Dominant-hand grip strength (kg)		
High impedance; one hand	36.2 (7.2)*	34.8 (7.7)
Low impedance; one hand	36.6 (6.8)	33.8 (7.8)
High impedance; two hands	35.4 (7.4)	35.1 (8.7)
Low impedance; two hands	35.6 (8.0)	35.4 (8.3)
Nondominant-hand grip strength (kg)		
High impedance; one hand †	32.7 (7.1)	32.5 (7.4)
Low impedance; one hand †	32.0 (7.3)	31.6 (7.4)
High impedance; two hands	32.7 (7.3)	32.8 (8.3)
Low impedance; two hands	32.7 (8.4)	32.6 (8.4)

*Values are mean (SD).

†These are 'control' values. The nondominant hand was not used to squeeze the bag.

There was a small but significant increase in coefficient of variation for tidal volume with time ($p = 0.03$, Table 1). There were no significant differences in coefficient of variation for levels of impedance ($p = 0.73$) or number of hands used to squeeze the resuscitator ($p = 0.90$). There were no significant interaction effects for the dependent variable coefficient of variation.

Discussion

Our finding of increased tidal volume delivery when two hands are used during manual bag-valve ventilation is not new, and is consistent with the work of our group and others.[2-6] As seen in Table 1 and Figure 1, the average tidal volume delivered with one-hand ventilation was less than the 0.8 L recommended by the American Heart Association.[9] Based upon the results of this study and others, we recommend that two hands be used with manual bag-valve ventilation devices whenever possible.

Our finding of decreased tidal volume with increased impedance is also consistent with similar work done by others.[1,2] Although the tidal volumes delivered were less with higher impedance, the average tidal volume delivered when two hands were used exceeded the American Heart Association recommendation of 0.8 L. Thus, it appears that the magnitude of the effect of using two hands to squeeze the resuscitator is greater than the effect of impedance.

Our data suggest that fatigue may have little effect on delivered tidal volumes, at least for ventilation periods up to 30 minutes. There is some evidence that fatigue was developing at the end of 30 minutes, as seen with the decrease in grip strength of the dominant hand (Table 2); this was particularly marked for one-hand ventilation. There also was a small increase in variability of tidal volumes after 30 minutes (coefficient of variation, Table 1), which may also indicate the development of fatigue. Although there was this evidence of impending fatigue, there was no decrease in tidal volume at the end of 30 minutes. In our study, the effects of impedance and the number of hands used to squeeze the bag were much greater than the effect of fatigue.

It is now known that many factors affect tidal volume delivery during manual bag-valve ventilation (Table 3). For this reason, it may be desirable to monitor the delivered tidal volumes when bag-valve resuscitators are used.[17,18] We notice that there is an interesting clinical paradox related to the use of manual bag-valve resuscitators. During mechanical ventilation, tidal volumes are routinely monitored. However, if the patient is removed from the ventilator and ventilated with a manual bag-valve device, tidal volumes are almost never monitored.

We used the same bag-valve resuscitator for this entire project so that the effect of resuscitator performance would remain constant throughout the project. We experienced no problems with the performance of the resuscitator during this study, and we doubt that changes occurred in the performance

Table 3. Potential Factors Affecting Tidal Volume Delivery from Manual Bag-Valve Resuscitators

Factors	References	Comments
Mask versus endotracheal tube	1, 6, 10-15	Volumes delivered during bag-valve-mask ventilation are often inadequate.
One hand versus two hands	2, 4, 5, present study	Higher volumes are delivered with two hands rather than one hand squeezing the bag.
Hand size	4, 5	Higher volumes can be delivered by persons with larger hands.
Lung impedance	1, 2, present study	Delivered volumes decrease with an increase in airway resistance and a decrease in lung compliance.
Resuscitator brand	5	Differences exist for delivered volumes among commercially available resuscitators.
Fatigue	Present study	Fatigue does *not* affect delivered tidal volumes for ventilation periods of 30 minutes or less.
Gloves	5	Wearing gloves does *not* affect delivered tidal volumes.
Operator skill	16	Skill and training of the operator affect the delivered tidal volume, especially with bag-valve-mask ventilation.

of the resuscitator that could have affected our results. We chose a resuscitator for the study that was *not* a single-patient-use disposable device, and thus was one designed for multiple usages. However, further work is needed to determine whether changes in the performance of a bag-valve resuscitator over its life span affect tidal volume delivery.

Further work would be of interest in this area. It would be interesting to evaluate the effect of fatigue with different commercially available manual bag-valve resuscitators. It has been shown that differences exist for delivered volumes among commercially available resuscitators.[5] The resistance through the valves of some bag-valve resuscitators has also been shown to be excessive, which could affect the delivered tidal volumes.[19] It would also be useful to evaluate the effects of higher respiratory rates on delivered tidal volumes. The effect of longer evaluation periods could also be evaluated, but the clinical importance of this may be questionable.

Conclusions

We found that tidal volume changes very little over a 30-minute period during use of a manual bag-valve resuscitator. The effects of lung impedance and using two hands to squeeze the resuscitator were greater than the effect of fatigue.

PRODUCT SOURCES

Test Lung:
TTL Model 1601, Michigan Instruments, Grand Rapids MI

Spirometer:
Model VM-90, Bear Medical Systems, Riverside CA

Calibration Syringe:
Jones Medical Instrument Co, Oak Brook IL

Adult Bag-Valve Resuscitator:
Laerdal Medical Corp, Armonk NY

Grip-Strength Tester:
MY-GRIPPER Digital Grip Strength Tester, Carolina Biological Supply Co, Burlington NC

Statistical Analysis Software:
SPSS/PC+, SPSS Inc, Chicago IL

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New Horizons VIII: Emerging Therapies for Respiratory Disorders

David J Pierson MD

Published in this issue of the Journal are the first three papers developed from the 8th annual "New Horizons" symposium, held December 12th in San Antonio during the 38th Annual Convention and Exhibition of the AARC. The 1991 symposium's focus was on new devices and monitoring techniques. The 1992 theme was new therapies, and a critical look was taken at six widely different treatments or therapeutic approaches—each one rapidly expanding, and each already affecting the practice of everyone who manages patients with respiratory disease.

Two of the six presentations were about new developments in management of the adult respiratory distress syndrome—one a biochemical-pharmaceutical strategy (surfactant therapy) and the other a new way of approaching conventional ventilator management (permissive hypercapnia). Two—lung transplantation and endoscopic procedures for therapy and diagnosis—highlighted dramatic recent developments in thoracic surgery. The fifth described the exciting and far-reaching developments in cystic fibrosis in just the last 5 years, encompassing pathogenesis, drug therapy, physical measures, and lung transplantation, plus the impending advent of gene therapy. Finally, less dramatic but potentially no less important, new developments in nicotine replacement via chewing gum and transdermal patch, as pharmacologic adjuncts to smoking cessation, completed the Symposium's presentations. This sampling of late-twentieth-century medical progress in therapies related to respiratory care illustrates the diversity and excitement of the profession, the rapidity of its expansion, and the importance of multidisciplinary collaboration in patient assessment and management.

The first of the three articles in this issue (by Stephen G Jenkinson) concisely reviews the current status of lung transplantation.[1] In the 10 years since improvements in surgical technique and the appearance of more effective immunosuppressive drugs made human lung transplantation a real option in the treatment of fatal lung disease, hundreds of patients, with an expanding array of disorders, have received transplanted lungs. Current outcome statistics are impressive. Generally considered only for patients expected to die within 1-2 years, lung transplantation by any of 4 different procedures (depending on the disease process and other factors) carries a 15-20% perioperative mortality and an overall 60-70% 2-year survival. Cost remains extremely high, and the limited availability of donor organs severely restricts the numbers of patients for whom this therapy can be a realistic prospect. Nonetheless, for those individuals able to return to a normal lifestyle following lung transplantation for disabling, end-stage pulmonary disease, the procedure truly constitutes a medical miracle.

Next comes Karen Ann Hardy's overview of our present understanding of and therapy for cystic fibrosis.[2] I vividly remember the discouragement and helplessness I felt, as a medical student 25 years ago, when participating in the care of a 5-year-old girl with terminal cystic fibrosis. Then, this most common, fatal, inherited disease of Caucasian Americans condemned its victims to a childhood death following years of progressive malabsorption and relentless pulmonary suppuration, and there was little that could be done. Today the median survival age is nearly 30 years, and more than a third

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of all patients are adults. Patients with cystic fibrosis enjoy normal nutritional status and attend multidisciplinary clinics where management includes new antibiotic regimens and bronchial hygiene techniques that slow the progression of their bronchopulmonary disease to an extent unimagined a generation ago. The exact intracellular mechanisms and genetic defects that cause cystic fibrosis are now known, and therapies targeted at the very pathogenesis of the disease are becoming available. Even for patients with end-stage pulmonary disease, lung transplantation now offers the prospect of renewed hope.

Finally, this issue's mini-series concludes with a review by Rennard and Daughton[3] of promising new weaponry for the battle against the biggest killer of all—tobacco-related disease. There is no question that smoking cessation holds more potential for lives saved and health preserved than any other health measure in the developed world, and that, as a global issue, it is as important to the readers of the Journal as any single endeavor. Although transdermal nicotine is no cure for cigarette smoking, there is increasing evidence that it can provide substantial help for many nicotine-addicted smokers who desire to quit. Rennard and Daughton have wide experience with nicotine replacement therapy and other aspects of the management of smoking cessation. They concisely review the rationale for nicotine replacement and summarize current data on its efficacy, and they offer practical pointers for using the new nicotine patches.

This year's "New Horizons" series concludes next month.

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Lung Transplantation–An Update

Stephen G Jenkinson MD

I. Introduction
  A. Donor Selection
  B. Recipient Selection
II. Transplant Operations
  A. Heart-Lung Transplantation
  B. Single-Lung Transplantation
  C. Double-Lung Transplantation
III. Postoperative Care
IV. Infection and Rejection
V. Outcome

Introduction

Improved surgical techniques and effective immunosuppression have revolutionized solid organ transplantation and have ushered in the beginnings of successful lung transplantation. Early attempts at lung transplantation were largely unsuccessful due to problems with rejection, pneumonia, and bronchial anastomotic breakdown. This trend began to reverse in the early 1980s when the Toronto Transplant Group began to report successful lung transplantation, with transplant recipients leading productive lives following their operations.[1]

The only indication for lung transplantation originally was severe interstitial lung disorders, but indications have now been broadened markedly as more experience with the techniques has been gained. Both obstructive and restrictive pulmonary disorders and severe pulmonary vascular diseases now qualify patients for lung transplantation. Recently, patients with a variety of systemic disorders primarily affecting the lung have also become candidates for lung transplantation, and their success rates and survival statistics are similar to the success rate of other types of lung transplantation patients.

Present lung transplantation operations available for the various disorders are (1) heart-lung; (2) single-lung; (3) double-lung; and (4) double-lung sequential. The single-lung techniques appear to be the most common application in all patients other than those with primary heart disease or pulmonary disease associated with chronic infection. This is due to the fact that a single-lung transplantation is the easiest operation, uses the smallest amount of transplanted tissue, and results in the shortest operative time.

Donor Selection

Rigid criteria have been established for choosing potential donors for lung transplantation procedures. Donors must (1) have been declared brain dead; (2) have family consent given; (3) have no history of cardiac, chronic respiratory, or malignant disease; (4) be younger than 45 years; (5) have a normal EKG and a normal chest radiograph; (6) have a partial pressure of arterial oxygen greater than 300 torr (with F_{IO_2} = 1.0 and 5 cm H_2O of positive end-expiratory pressure, or PEEP); and (7) be HIV- and

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hepatitis-negative on serologic testing. Lung tissue removed from a donor is cultured and a gram stain is performed on sputum or secretions obtained by bronchial lavage. Cytomegalovirus (CMV) serology is also tested and CMV-negative donor tissues are given to CMV-negative recipients if possible. Donor and recipient must be ABO compatible and have lungs of approximately equal size.

Recipient Selection

Prospective transplant recipients should have debilitating lung disease that most probably limits their life expectancy to 1.5 to 2 years. They are thoroughly screened when first considered for lung transplantation and should exhibit (1) a stable psychosocial profile; (2) no alcohol or drug abuse; (3) normal hepatorenal function; (4) negative serologic testing for HIV and hepatitis B; (5) the ability to relocate if necessary to be near the transplant center while awaiting transplantation; and (6) normal cardiac function on assessment that includes cardiac catheterization to rule out significant coronary atherosclerosis. Other criteria used for recipient selection include an age of less than 60 years and absence of respiratory failure requiring mechanical ventilation (although some patients who require some short-term ventilator support have been successfully transplanted). Patients with systemic pulmonary disorders that involve mainly the lung are now being considered on an individual basis as possible lung transplant recipients. A number of patients with systemic disorders that involve the lung have been successfully transplanted.[2]

Transplant Operations

Heart-Lung Transplantation

Indications for heart-lung transplantation (HLT) include primary pulmonary hypertension, pulmonary disease with noncorrectable Eisenmenger's syndrome, pulmonary disease with unrelated cardiac disease, and cystic fibrosis. The supply of donor organs for HLT is obviously much more limited than is the single-lung supply. One of the most significant problems encountered with HLT is the high incidence of graft rejection or obliterative bronchiolitis that occurs in these patients following transplantation. Bronchiolitis obliterans is the progressive submucosal scarring of membranes and respiratory bronchioles. Incidence of obliterative bronchiolitis is reported to be as high as 50% in HLT patients and can necessitate a second transplant procedure that is technically very difficult because of pleural adhesions and mediastinal scarring occurring after the initial operation.

Surgery for HLT requires cardiopulmonary bypass and is performed through a median sternotomy. A similar dissection is performed on the donor. The transplant is completed by anastomosing the trachea above the carina, the right atrium, and the donor and recipient ascending aortas. Breakdown of the tracheal anastomoses is not a common problem despite the fact that the bronchial arteries are not reanastomosed during this procedure.

Indications for HLT have been decreasing due to a number of factors:[3] (a) a heart-lung donor could provide organs for three transplant recipients (2 lungs and a heart); (b) cardiopulmonary bypass can be avoided in single-lung or double-lung procedures; (c) cardiac denervation is avoided by lung transplantation only; (d) waiting time for HLT in patients is as long as 6 times that required for lung transplantation alone; and (e) cardiac complications of chronic transplantation such as rejection or coronary sclerosis appear to be much less prevalent with single-lung or double-lung transplantation than with heart-lung transplantation.

Single-Lung Transplantation

At the present time, single-lung transplantation (SLT) is being performed for restrictive, obstructive, and pulmonary vascular diseases. The procedure is not used for septic lung diseases such as cystic fibrosis or severe bronchiectasis because the remaining native septic lung would infect the newly transplanted lung, particularly when the patient becomes immunosuppressed.

The restrictive lung disorders that are being treated by SLT include (a) idiopathic pulmonary fibrosis (IPF); (b) interstitial pneumonitis; (c) sarcoidosis; (d) scleroderma (with effects limited primarily to the lung); (e) pneumoconioses; and (f) drug-induced pulmonary fibrosis. Patients with obstructive lung disease who are candidates for SLT include those with (a) emphysema, either centrilobular (COPD)

or panlobular (α_1-antitrypsin deficiency); (b) bronchiolitis obliterans; (c) eosinophilic granuloma; or (d) lymphangioleiomyomatosis.[4]

Pulmonary vascular diseases that are being treated with SLT include primary pulmonary hypertension (PPH) and, disorders producing Eisenmenger's physiology.[5] Marked physiologic abnormalities in right-heart function in these patients have been noted to rapidly return toward normal following lung transplantation, and patients have been shown to have normal exercise tolerance following their lung transplant procedure.

Exercise studies measuring pulmonary function and cardiovascular/ventilatory responses in SLT recipients who had been transplanted 6 months earlier for either obstructive or restrictive lung disease revealed that the patients do not have ventilatory limitations during exercise but they do have markedly decreased maximum exercise capacity ($\dot{V}_{O_{2max}}$).[4] No significant differences in exercise responses were reported between the obstructive and the restrictive transplant recipients.

Double-Lung Transplantation

Double-lung transplantation (DLT) was first performed for obstructive lung disease, but now is performed mainly for patients with chronic septic lung disease, including cystic fibrosis or bronchiectasis.[6] The procedure is performed en bloc through a median sternotomy and has produced significant anastomotic complications, including airway stenosis. Complications can sometimes be treated with YAG laser therapy or placement of a tracheal stent to maintain the patency of the airway.

Because of these problems, the use of a new technique known as double-lung sequential-single transplantation has increased recently. Recipient surgery in these patients is performed through bilateral thoracotomies, with each lung implanted separately. Two bronchial anastomoses and four vascular anastomoses are required. This procedure eliminates the use of cardiopulmonary bypass and results in a decrease in postoperative airway stenosis.

Postoperative Care

Patients return from surgery intubated and requiring mechanical ventilation. The F_{IO_2} is maintained at a level to sustain oxygen saturation at or above 95% while the patient is receiving 5 cm H_2O of PEEP and the transplanted lung is positioned uppermost. The ventilator can usually be discontinued within 24 to 36 hours after surgery. Patients are supported by parenteral nutrition following surgery because postoperative paralytic ileus is common and may persist for a number of days.

Renal function is carefully monitored in postoperative transplant patients due to the nephrotoxicity of many of the transplant-related drugs, including cyclosporine and azathioprine. The development of oliguria requires immediate lowering of the dose of cyclosporine being administered. Prophylactic antibiotics are also administered at the time of surgery. Trimethoprim/sulfamethoxazole is given as *Pneumocystis carinii* prophylaxis and ganciclovir as CMV prophylaxis if either the patient or the donor were CMV-positive prior to surgery.

The regimen for immunosuppression varies among different transplant centers but includes combinations of steroids, azathioprine, cyclosporine, and antilymphocyte globulin. Many centers are now also administering steroids immediately following transplantation, with no recognizable problems in wound healing.

Infection and Rejection

The two major ongoing complications of lung transplantation are the development of lung infection and graft rejection following the transplant procedure.[7] The immunosuppression required in these patients produces an increased risk for the development both of routine types of infection and of more uncommon opportunistic infections seen in other types of immunosuppressed patients. Chest radiographs do not clearly separate rejection from infectious processes, but this distinction is critical in applying specific therapy.

Patients must be monitored on a regular basis and aggressive diagnostic techniques must be applied if infection is suspected. CMV infection is an especially common problem in lung transplant patients. Ganciclovir therapy does not appear at present to be totally effective treatment for CMV infections in symptomatic lung transplant recipients, and this infection produces a great deal of morbidity and mortality.

Rejection of the transplanted lung tissue can occur either acutely or chronically and can be associated with the development of obliterative bronchiolitis. Obliterative bronchiolitis can occur at any time after the first 2 months following transplantation. The etiology of obliterative bronchiolitis remains unclear. The diagnosis of rejection in lung transplant recipients is made by tissue biopsy (usually transbronchial) and has recently been standardized by applying a universal scoring system. The Lung Rejection Study Group has recommended that a minimum of five transbronchial specimens of lung be obtained in order to diagnose rejection. Acute rejection is characterized by perivascular and interstitial mononuclear infiltrates. Chronic rejection shows evidence of bronchiole destruction. CMV infection can also be associated with lymphocytic infiltrates and can pose a problem in differentiating rejection from infection.

Outcome

Operative mortality for lung transplantation is approximately 16% for heart-lung, 19% for single-lung, and 17% for double-lung recipients. Reasons for mortality include graft failure, anastomotic complications, cardiac complications, hemorrhage, and the development of the adult respiratory distress syndrome. Death in the first 6 months is usually due to infection. After 6 months, rejection is the major cause of both morbidity and mortality.

The 2-year actual survival associated with lung transplantation has been reported as approximately 67% for SLT and 60% for DLT or HLT. Individual series have reported 1-year survival rates of 77-90% for single-lung recipients and 80% for bilateral lung-recipients (author's unpublished survey).

The future of lung transplantation remains very bright, with the potential for the rapid growth of transplantation. The problems that remain to be addressed include the shortage of donors, problems with diagnosis and treatment of rejection and infection in transplant recipients, relatively short preservation times for lung tissue, and financial cost to our health care system. As our experience with lung transplantation increases, we hope to continue to improve the delivery of care and the prevention of complications in these transplant recipients.

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Advances in Our Understanding and Care of Patients with Cystic Fibrosis

Karen Ann Hardy MD

I. Introduction
II. History
III. The Disease
  A. Pathophysiology
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Introduction

Cystic fibrosis, the most common, fatal, autosomal-recessive disease of Caucasian Americans, has been recognized for many years. Important advances in our understanding of the genetics and pathophysiology have occurred since 1987. These are stimulating the development of new techniques for improved care, both medically through drugs, diagnostically through genotypic and phenotypic correlations, mechanically through new airway clearance techniques, and surgically through changes in end-stage management. The excitement of new discovery has expanded the numbers of caregivers attending to cystic fibrosis patients of all ages. Scientists are racing to clarify our understanding of the basic defect, its relationship to pathophysiology, and management strategies. The number of articles published relating to cystic fibrosis has probably increased 60% in the past 5 years. Reasonable optimism floods the field at all levels.

History

References to cystic fibrosis were made in the German folklore thousands of years ago.[1] Further definition of this abnormality did not occur until the characteristic abnormalities of the pancreas and gastrointestinal tract were documented by Landsteiner in 1905.[2] It was not until 1938 that Dorothy Anderson published her landmark observations on pathologic specimens from a number of infants who died during a heat wave in New York City.[3] She was the first to tie together the fibrocystic changes of the pancreas and the relationship between acute dehydration and death. Shortly there-

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after, the electrolyte abnormality of sweat containing a large quantity of sodium chloride was clarified, and the sweat test was refined by Gibson and Cook in 1959.[4] At that time, the use of mist tents, Mucomyst (N-acetylcysteine), colistimethate (Colymicin), and low-fat diets barely changed the poor nutritional status, severe lung disease, and early death of these patients. Major advances in care for patients occurred with the center/interdisciplinary team concept furthered in the United States, including chest physical therapy, aggressive antibiotic treatment, high-fat high-calorie diets, pancreatic enzyme supplementation, and increased attention to exercise, resulting in significant lengthening of the life span.

In the early 1980s, Quinton discovered the chloride-channel defect in cystic fibrosis epithelial cells.[5-7] Many investigators collaborated and simultaneously discovered the gene in 1989.[8-10] They localized the cystic fibrosis gene to the long arm of chromosome number 7. Following the release of this information, we have seen the rapid development of the mouse model for cystic fibrosis described in *Science* this year (1992).[11] These mice actually carry the most common defective CF gene and are able to reproduce in an autosomal-recessive pattern with a one in four risk of affected progeny. Unfortunately, mouse respiratory tract epithelium is unlike human epithelium—with far fewer mucus cells—and the major manifestation of cystic fibrosis in these mice is gastrointestinal in nature rather than respiratory. Viral transfection of the gene was reported in 1992 in *Nature,* with a description of the insertion of a normal human gene into the cultured CF respiratory tract epithelium.[12] The normal gene is capable of activating the production of normal human cystic fibrosis transmembrane regulator (CFTR) protein, the product of the CF gene.[12]

These discoveries are extremely important to our understanding of the disease processes of cystic fibrosis and to the development of new treatment strategies. The community of cystic fibrosis caregivers has entertained new ideas for treatment and has become organized to perform multicentered, carefully designed national trials to establish which new treatment strategies of the coming decade will be safe and effective. We hope that quality of life and survival will continue to improve as successful new treatments are established.

The Disease

Pathophysiology

The CF gene (present in all human beings) is defective in about 1 of 20 Caucasians but less often in peoples of other races. Two copies of the gene are present on each chromosome number 7, and both must be defective for an individual to suffer from cystic fibrosis. Carriers with a single abnormal copy of the cystic fibrosis gene are physically normal and are able to produce sufficient quantities of the cystic fibrosis gene product to allow normal ion movement across epithelial cells.

The protein CFTR is a chloride channel. Defective CF genes cause abnormal CFTR to be produced or result in the absence of CFTR, causing abnormal chloride movement across epithelial cell surfaces. Because the movement of water follows that of chloride, this defect in chloride transport results in the relative lack of water movement and consequent dehydration of secretions at epithelial cell surfaces. The CF gene is expressed in certain cells throughout the human body, most notably the respiratory epithelium, gastrointestinal epithelium, and all foregut epithelial membranes. Submucosal glands produce the largest quantity of CFTR in the respiratory tract, and important expression is found in the uterine wall and the kidney (for reasons that are not clear). Patients who have cystic fibrosis suffer from the relative dehydration of secretions in some of these target organs and, therefore, have the characteristic clinical manifestations of lumens obstructed by thick secretions. Organ systems commonly involved include the respiratory tract, gastrointestinal tract (including the pancreas, liver, and gall bladder), reproductive organs, and sweat glands.

Clinical Manifestations

Patients with cystic fibrosis often present with respiratory tract illness or failure to thrive. Most patients are diagnosed when they are infants or youngsters less than 2 years of age (Table 1). Clarification of the gene abnormality has resulted in our recognition of various forms of cystic fibrosis with many fewer symptoms. An example is "congenitally absent bilateral vas deferens syndrome," which

Table 1. Demographic, Clinical, and Microbiologic Information from the Cystic Fibrosis Foundation*

Number of patients registered	18,926
Mean age at diagnosis	2.8 years
Median survival age	29.4 years
> 18 years of age	33%
Caucasian	95%
Not covered by insurance	2.4%
Treated with home I.V.	13.8%
Organisms colonizing patients	
Pseudomonas aeruginosa	59.9%
Pseudomonas cepacia	3.5%
Staphylcoccus aureus	28.6%
Using digestive enzymes	91%

*Cystic Fibrosis Foundation, Patient Registry 1991, Annual Data Report, Bethesda MD, October 1992.

has only this manifestation of the CF gene abnormality and is diagnosed in the adult.

For many years, care for cystic fibrosis patients has been focused on the respiratory tract abnormality because it is this abnormality that most often leads to death. Nutritional support and attention to malabsorption associated with pancreatic insufficiency has also been a major focus. Many complications still plague patients including diabetes mellitus, sinusitis, polyposis, cirrhosis, pneumothorax, hemoptysis, and respiratory failure.

New Strategies for Treatment

Background

Knowledge of the function of the CF gene and our improved understanding of pathophysiology focus attention toward new therapeutic strategies for cystic fibrosis. These strategies include treatment of infections with new antibiotics of both intravenous, oral, and inhaled types, to combat infection in the lung. Anti-inflammatory drugs to try to decrease the inflammatory response in the respiratory tract epithelium have also been the subject of recent large clinical controlled trials. Augmenting the immune defense by vaccinating individuals against pseudomonas, one of the most common bacterial infections, is the subject of a new clinical trial that began in January 1993. Pilot studies looking at supplemental gamma globulin to passively improve a patient's immune defense have been promising. New airway clearance techniques are being evaluated. Patients with cystic fibrosis have thick and sticky secretions, and for many years airway clearance has been enhanced by conventional postural drainage, percussion, and vibration. Techniques such as autogenic drainage, positive expiratory pressure, and the flutter valve are subjects of current research internationally. Drugs that thin secretions should be released soon. Altering ion movement to address the basic defect and to rehydrate secretions is another avenue being explored. Transplantation of healthy lungs and even gene therapy are now becoming a reality for a number of patients. We hope that the insertion of functionally normal CF human genes into certain target locations will critically affect the patient and lead to normalization of the basic protein production so that ion movement normalizes and the initial cascade of events ceases or never occurs. Organized controlled clinical trials (which have either been completed, are ongoing, or are anticipated) should help us understand all of these new therapeutic frontiers. These are carefully designed, prospective, randomized, double-blind studies that have been funded both through the Cystic Fibrosis Foundation and the National Institutes of Health and other organizations to answer questions regarding safety and efficacy for many of the above new treatments.

Antibiotics

Recent antibiotic changes have occurred with the development of ciprofloxacin, a quinolone antibiotic that is effective against *Pseudomonas* species and is extremely well absorbed orally. Ciprofloxacin was the first medication with this capability, and other quinolones have subsequently been developed that are also effective against *Pseudomonas* species. Clinical trials comparing the efficacy of oral ciprofloxacin and I.V. antibiotics have shown oral ciprofloxacin to be effective in controlling pseudomonas pneumonia; however, resistance to this antibiotic develops relatively commonly and limits its long-term usefulness.[13] Clinical applications have generally involved intermittent rather than chronic use of ciprofloxacin.

The question of use of antibiotics for infants newly diagnosed with cystic fibrosis has been studied for the past 4 years in a NIH-funded trial. Patients receive daily placebo or cephalexin (Keflex) to combat *Staphylococcus aureus* infections, the usual first colonizing agents for cystic fibrosis children. Thus far, in the 200 patients enrolled, no clear increase in resistance to this antibiotic has occurred, and regular sputum cultures are being obtained. Many organisms from cystic fibrosis patients are now available in the microbiology laboratory at Memorial Miller Children's Hospital in Long Beach for use in antibiotic development and efficacy studies. The results of the cephalexin study will not be available until all children reach the age of approximately 6 years, when they can reliably perform pulmonary function testing, the primary outcome determinant for this study. We hope that the study will be completed and results available during 1993. Meanwhile, research on antibiotic development directed against this large repository of specimens is ongoing, and shared samples are available to other centers for testing. A number of cephalosporins and other antibiotics are being tested.[14,15] Finally, inhaled antibiotics are being utilized on a more regular basis for cystic fibrosis patients. This was begun many decades ago but was not found to be particularly useful. In this decade, the results of research regarding the deposition of aerosols and the types of equipment available for delivery of aerosolized medication has been expanded. Inhaled aminoglycosides and ureidopenicillins have been tested and found to be helpful in maintaining improvement following I.V. antibiotic therapy.* They have also been utilized in acute exacerbations to allow home therapy and avoid hospitalization. Finally, technical advances in various types of permanent catheters have allowed patients of all ages to receive antibiotic therapy in home settings, preserving patients' abilities to attend school or work.

*Abstract by Ramsey B, Smith A, Williams-Warren J, Astley S, McBurnie M, Hedges D, "The Efficacy of Aerosolized Tobramycin Administration in Cystic Fibrosis Patients: Results of a Multi-Center, Placebo-Controlled, Cross-Over Trial" from the 6th Annual North American Cystic Fibrosis Conference entitled "Advances in Clinical Therapies" held in Washington DC, October 17, 1992.

Anti-Inflammatories

Anti-inflammatory trials have included a controlled study of the use of prednisone for patients with cystic fibrosis. This study funded by the Cystic Fibrosis Foundation was recently completed.† Patients between 7 and 11 years of age with cystic fibrosis were randomly assigned to one of three groups receiving either placebo, prednisone at 1 mg/kg every other day, or prednisone at 2 mg/kg every other day. After approximately 3 years, the high-dose group was eliminated because ombudsmen following the study saw an unacceptable number of complications in this group. These complications included diabetes and growth retardation as well as cataracts. After completion of the 4-year study, improvement in pulmonary function could be seen in the group treated with 1 mg/kg every other day versus the placebo group. This was seen in the vital capacity at every annual evaluation and in the FEV_1 at 1-year evaluation. Careful evaluation of the relative benefit and the complications of the use of steroids in this population is recommended. Final analysis and publication of this study is pending. In a like manner, an ibuprofen study modeled after the steroid study has been initiated and is ongoing. It is hoped that this nonsteroidal anti-inflammatory will also be beneficial but will be less toxic.

Immune Globulins

In one double-blind study, patients hospitalized for exacerbations of their pulmonary disease received routine care with antibiotics and vigorous airway clearance and either small doses of intravenous gamma globulin or a placebo. There was some improvement in pulmonary function in those receiving the gamma globulin. Therefore, a larger trial is being initiated.[16] In the initial phases of the larger trial, patients will be passively immunized with gamma globulin and, following this, it is anticipated that a placebo-controlled trial will proceed including passive standard gamma globulin in-

†Presentation by Beryl J Rosenstein MD, Johns Hopkins University Hospital, "Alternate Day Steroid Trial" during the 6th Annual North American Cystic Fibrosis Conference held in Washington DC on October 17, 1992.

fusions compared to hyperimmune globulin against *Pseudomonas* species.[17]

Airway Clearance Techniques

The airway clearance techniques initiated in the 1950s—postural drainage, percussion, and vibration—have never been subjected to large rigorous controlled studies in the manner now considered appropriate. Very small studies looking at immediate effects have been performed, and short-term studies have shown that lack of any airway clearance technique can be associated with deterioration in pulmonary function. A 3-week crossover design study[18] showed that single therapies can improve pulmonary function to baseline levels. More recently, new techniques have been developed to improve the clearance of airway secretions. Physiologic considerations have included the presence of severe dynamic compression of the damaged airway in cystic fibrosis patients that results in decreased clearance. The change in the airway compliance as airway wall destruction increases due to chronic infection has contributed to poor airway clearance and movement of the equal pressure point during coughing. A number of techniques listed in Table 2 have been used in an attempt to circumvent this problem, in order to maintain airway patency.

Table 2. Airway Clearance Techniques Used in Cystic Fibrosis Patients

Postural drainage, vibration, percussion (PDVP)
Forced expiratory technique (FET)
Positive expiratory pressure (PEP)
Mask
Mouthpiece
Flutter valve
Inflatable, percussive vest
Active cycle of breathing (ACB)

The forced expiratory technique (FET) is a form of modified cough. The patient is instructed to leave the glottis open and forcibly exhale, often saying "huff." Patients often combine this maneuver with other airway clearance methods.[19] Active cycle of breathing (ACB) is a similar technique used in Europe. The positive expiratory pressure (PEP) mask has been utilized in Europe and in the United States and allows the patient to develop a positive end-expiratory pressure with a valved mask or mouthpiece.[20,21] Pressures of 10 to 20 cm of water are commonly utilized, based on initial research that looked at re-expansion of atelectatic lung from autopsy specimens.[5] Additional high pressure studies have been reported by Oberwaldner et al, with pressures as high as 60 cm of water pressure.[22] Patients perform a series of inspiratory and expiratory maneuvers utilizing their one-way valves following a series of approximately 20 breaths. Typically, exhalation is forcibly prolonged to triple inspiratory time. Subjects perform three to five "huff" coughs with FET. They return to the PEP treatment, cycle through another 20 breaths, and repeat this for a total of 20 minutes (in most studies) or until their active production of sputum decreases. Autogenic drainage proposed a few decades ago and championed by Jean Chevalier in Belgium is a technique that does not require any supplemental devices. This is a form of biofeedback that allows the patient to breathe at certain lung volumes with certain respiratory patterns so that controlled ventilation helps mucus move forward to larger airways and FET allows improved clearance of these secretions.[23] Figure 1 shows the lung volumes the patient utilizes during breathing for the three levels of autogenic drainage. This technique requires good concentration and typically patients must be adolescent or older in order to learn the technique. The addition of auditory and visual aids to provide biofeedback during training is extremely helpful when teaching patients autogenic drainage.[24]

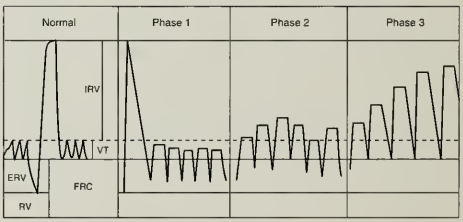

Fig. 1. Phases of autogenic drainage shown on a spirogram of a normal person. Phase 1: unstick; Phase 2: collect; Phase 3: evacuate. V_T = tidal volume; ERV = expiratory reserve volume; RV = residual volume; FRC = functional residual capacity; IRV = inspiratory reserve volume; and IRV + V_T – ERV = vital capacity.

The flutter valve was designed in Sweden, is widely utilized there, and is undergoing FDA evaluation in the United States. This technique utilizes a small pipe-like device that has a heavy metal ball rotating freely within the pipe. Patients inspire and actively exhale into the pipe. This generates a positive expiratory pressure as well as oscillations that are transmitted to the airways as the ball rotates and flutters inside the pipe. Formal studies of this technique are not yet available in the United States, although a pilot study looking at this technique is now underway at our institution. Further clarification of the benefit of various airway clearance techniques will be extremely important because none of the newly proposed treatments will eliminate the problem of increased secretions entirely, and clearance of these secretions will always be important.

Mucolytics

Mucolytic therapy has made rapid advances recently. A number of inflammatory products are present in cystic fibrosis mucus and cause damage to airway walls. These include neutrophil elastase and proteases. Inhibitors of these substances can be inhaled in an attempt to modify the inflammatory response in the airway. Controlled trials with secretory leucocyte protease inhibitor (SLPI) and ICI 200-880, an anti-elastase, are ongoing. Pulmonary function, safety, dose range, and efficacy studies will soon be available. A short-term study does document increases in elastase and protease activity.[25]

Cystic fibrosis patients who are colonized with bacteria gain large quantities of DNA in their sputum from the destruction of neutrophils and bacteria. DNA causes increased mucus stickiness, and a synthetically produced DNAse has caused much excitement in the CF world recently; recent studies utilizing this product for inhalation have looked at dose ranges, safety, and efficacy on a short-term basis. Patients generally have had an improvement in pulmonary function with increases of 10 to 15% in their vital capacity and FEV_1.[25] The Phase-3 trial is expected to be completed in March 1993, and it is hoped that FDA approval of this drug can be gained shortly thereafter. Long-term toxicity of this synthetic preparation has not yet been studied.

Ion Movement Inhibitors

Amiloride inhibits the movement of sodium across epithelial surfaces. It has been utilized as an approved diuretic in the United States and more recently has been shown to change ion flux across epithelial surfaces and targeted cells in cystic fibrosis patients. In a small, controlled study it did alter the movement of ions when inhaled so that the inhibited sodium movement also resulted in improved hydration of secretions. Mucus studies were included in the analysis during this clinical trial and did reveal changes in the character of the mucus. Slight improvement in pulmonary function has been documented with this drug.[26] The effects of this drug can be amplified with triphosphate nucleotides, and new trials utilizing the triphosphate nucleotide UTP and amiloride will be underway in 1993. Bronchoscopic studies (even in young children aged 4 to 11) have shown that administration of amiloride aerosols do result in high levels of amiloride in the lung fluid.[27]

Organ Transplantation

Organ transplantation has evolved rapidly in the past few decades.[28] Lung transplantation has been very difficult, but greater successes have occurred through the late 1980s and early this decade.[29] Initially, cystic fibrosis patients typically chose heart-lung transplantation when this was technically the most common procedure performed. Transplantation does allow CF patients to experience longer and healthier lives. Operative mortality is decreasing significantly and technologic advances are dramatically changing the types of patients who are able to be considered for lung transplantation. Bilateral single-lung transplants with bronchial anastomoses and the 'clam-shell' procedure to avoid cardiac bypass have been great strides in this area. A small number of excellent transplant centers have been established, with the largest experience with cystic fibrosis patients found at Brompton Hospital in London. The donor lungs do not have the genetic abnormality causing cystic fibrosis and, therefore, do not develop the pathology of CF. However, complicating pseudomonas pneumonias and bronchiectasis can develop in donor lungs if the patient has severe sinus infections. Addi-

tionally, the trachea and both main-stem bronchi are still native and do have the basic abnormalities favoring colonization with pseudomonas. More than 250 patients with cystic fibrosis have now been transplanted, with a 63% 1-year survival and a 55% 2-year survival.* Survival rates among transplant centers vary.

Finally, some steps in gene therapy are now possible. Mice and rats have been utilized for this procedure, and research is rapidly advancing. The principles include targeting certain tissues and packaging the desired gene in some vector for transmission. Retroviruses, which require dividing cells, have been found unsatisfactory for this technique. Altered adeno-associated viruses and liposomes have proven to be successful vectors to facilitate gene transfection. Various markers and promoters are inserted with the CF gene to identify successful transfers. The adenovirus is tropic for respiratory tract epithelium and when it is neutralized to remove its virulence, the human CF gene can be inserted into the viral genome. The animal can then inhale the vector, with successful transfection of the gene into the respiratory epithelial cells. Production of the normal human CFTR then does occur as documented by various color-coded markers. Research looking at the length of time that the gene is expressed and the percentage of cells that are transfected will be important determinants in future clinical trials. It is hoped that a number of other problems such as penetration of inhaled vectors through the typical milieu of the mucus-lined airways of cystic fibrosis patients can be overcome. Potential toxicities of this type of therapy include the development of antibodies to this antigen (ie, allergy to the product) or reversion of a virus to a virulent strain. Long-term complications are not known. Further research is needed to answer these questions.

Mouse models that carry the cystic fibrosis defect and replicate in a reliably autosomal-recessive fashion have been successfully produced. New animal models attempting to mimic the cystic fibrosis pulmonary disease are being developed rapidly,[30] and it is hoped that gene transfection utilizing these models will be completed to clarify answers to important questions of safety and efficacy prior to human studies.

*From Mary S Pohl RN, Clinical Trials Nurse Specialist, Thoracic Surgery, St Louis International Lung Transplant Registry at Washington University School of Medicine, St Louis MO, February 1993.

In Conclusion

This is a time of great excitement for cystic fibrosis patients, families, and caregivers. Advances in our understanding of the pathophysiology have been breathtaking in the past 5 years, and improved therapies in the next decade should result in even more amazing changes in survival statistics and the quality of life for these patients.

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Transdermal Nicotine for Smoking Cessation

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I. Introduction
II. Nicotine Polacrilex
III. Transdermal Nicotine Systems (Patches)
A. Efficacy Data
B. Adverse Events
IV. Summary Comments

Introduction

Smoking has been recognized for many years as a deadly habit. Despite the fact that most smokers wish to quit, it is exceedingly difficult to do so for several reasons. First, nicotine is a potent, psychoactive drug.[1] Through actions directly on the brain's mesolimbic-dopaminergic system, nicotine provides smokers with a pleasurable, rewarding sensation.[1] As a euphoriant, nicotine is more potent, on a milligram-for-milligram basis, than cocaine, morphine, or amphetamine.[1] Second, as with other psychoactive drugs, once use of nicotine is habitual, a withdrawal syndrome with unpleasant symptoms is frequently a prominent feature of nicotine cessation or reduction.[2,3] Third, because of the ease and frequency of the use, cigarette smoking becomes an ingrained habit, associated with many activities of daily life. Thus, a smoker who wishes to quit faces the difficult problem of losing a pleasurable activity, modifying a frequently practiced behavior, and dealing with symptoms of nicotine withdrawal.

Nicotine administration as an aid to smoking cessation is designed to help ameliorate the symptoms associated with nicotine withdrawal. These symptoms are thought to develop when blood nicotine levels fall below certain threshold levels.[1] In contrast, the pleasurable sensations associated with nicotine are thought to depend both on the peak levels of nicotine achieved following smoking and on the rate of increase in blood nicotine.[4] Smoking a cigarette results in very rapid absorption of nicotine through the lungs with direct delivery into the arterial circulation.[1] Exceedingly high levels can, therefore, be achieved in the brain without loss due to hepatic metabolism. The cigarette is thus well designed to administer nicotine for its psychoactive addicting effects. A different pharmacokinetic delivery of nicotine would be desirable for prevention of withdrawal, if the system could provide relatively stable steady-state plasma nicotine levels but avoid the highly reinforcing nicotine "rushes" common to cigarette smoking. Nicotine polacrilex and transdermal nicotine systems were designed with this goal in mind.

Nicotine Polacrilex

The first form of nicotine replacement therapy approved for use in the United States was nicotine polacrilex. In this formulation, nicotine is bound to a polacrilex gum resin. The nicotine is released from the gum on chewing and can be directly absorbed through the buccal mucosa. The rate of nicotine absorption depends on the rate of chewing and, importantly, on the pH of the mouth: An acidic pH inhibits nicotine absorption. The total dose of nicotine depends on the number of pieces of gum chewed. Swallowing saliva containing nicotine delivers the active drug to the stomach where con-

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centrations can be locally high and can result in some side effects. Nicotine absorbed through the gastrointestinal tract is largely metabolized during the first pass through the liver and does not result in effective blood levels as does absorption through the buccal mucosa.

With proper instruction on the use of nicotine polacrilex, many smokers have had considerable benefit from the nicotine gum. Use of the gum in conjunction with a behavioral modification program, in a setting supervised by a specialist in smoking cessation, can result in abstinence rates approaching 35-40%.[5,6] Disappointing results in general practice settings have been related both to lack of behavior modification programs and to poor instruction in the use of the pharmaceutical.

Transdermal Nicotine Systems (Nicotine Patches)

Topical administration of pharmaceuticals is possible if compounds are of sufficiently low molecular weight and have appropriate solubility and stability characteristics that permit their direct absorption through the skin. Four different transdermal nicotine systems have been approved for use (as of December 1992) in the United States. These systems are based on a similar design: Nicotine is contained in a reservoir within the patch. An adhesive holds the device on the surface of the skin permitting the nicotine to diffuse from the reservoir through the skin and into the venous circulation. The patches differ in the rate at which nicotine is released from the device to the skin surface. As a result, there are some differences in the pharmacokinetic profiles of the various patches. Whether these differences will have important clinical implications remains to be seen. Information available to date, however, suggests that the various devices are similar in their clinical effects.

Because nicotine is volatile, each device contains a seal that prevents loss of active drug. After removal of the device from its package, the sealing layer must be removed. This permits the diffusion of nicotine from the device and, as a consequence, the device should be used promptly. The patch should be applied to a clean, dry, hairless skin area, generally on the trunk or upper arms. Areas where the skin is inflamed, irritated, or otherwise abnormal, should be avoided. It is recommended that application sites be rotated (Table 1). Because of its ease of application, transdermal nicotine administration has many advantages over other forms of nicotine replacement therapy.

Efficacy Data

A number of studies have now been conducted demonstrating the efficacy of transdermal nicotine administration as an aid to smoking cessation.[7-13] These studies show a remarkable similarity in their results. Seventy per cent or more of individuals can achieve abstinence in the first 2 weeks of nicotine

Table 1. Pragmatic Suggestions for Nicotine Patch Users

1. Do not commence patch use until your Quit Day. As a patch user, you will have two goals: (a) to use the patches maximally (check manufacturer's recommendations) to help you quit; (b) to get off the patches to become nicotine-free.
2. Rotate the patch to a new site daily. Avoid using the same skin site for 7 days.
3. Do not apply the patch prior to bedtime to avoid receiving high levels of plasma nicotine during sleep hours when most smokers need it the least. If the patch falls off and is lost during the morning or afternoon, reapply another patch. If the patch detaches prior to bedtime, do not apply a new patch unless you genuinely feel that the patch is necessary.
4. Pay attention to how your body responds to the patch. (a) If you develop troublesome insomnia or disturbed sleep while wearing a 24-hour patch, discontinue wearing the patch during bedtime hours. (b) Do not attempt to taper your patch use prematurely. Generally speaking, most smokers will respond to 6 to 10 weeks of total patch therapy.
5. Do not continue to use the patches: (a) if you become pregnant or if you are experiencing any severe skin reactions (severe erythema, edema, or generalized rash) or any other adverse events that you feel might be related to the patches; (b) beyond the manufacturer's recommended limit; (c) if you are still smoking (even one cigarette a day) after 2 weeks on the patches. The patches are recommended only as an adjunct to total cessation.

replacement.[14] Unfortunately, even with full-dose treatment, the number of abstinent individuals declines to 40-60% by 4 to 6 weeks.[10,13] These quit rates are, however, approximately twice that achieved with placebo patches in similarly motivated individuals undergoing identical behavioral programs.[14] Long-term follow-up continues to show this advantage of nicotine treatment over placebo even when transdermal nicotine is weaned and stopped.[10,11,13] Abstinence rates at 6 months are in the 20-40% range.[14]

Transdermal administration of nicotine is designed to help ameliorate the symptoms of nicotine withdrawal. To this end, it appears to be only partially effective. Symptoms of nicotine withdrawal are generally somewhat less severe in subjects receiving nicotine replacement than in subjects receiving placebo.[10,13,14] Importantly, the symptom of craving for tobacco seems to be less.[13] However, transdermal nicotine administration does not completely prevent symptoms of withdrawal. Whether higher dose formulations would be more effective, or whether different weaning strategies would have other advantages, is a subject of active research.

Adverse Events

The most common side effects of transdermal nicotine systems are related to local skin problems and difficulties with sleep. Local skin irritation (including mild erythema, pruritus, burning, or edema) is often either self-resolved or responds to simple therapeutic measures.[14] Cessation of therapy is not required. True hypersensitivity, however, has been reported in 2-3% of individuals. In these cases, a skin rash will reliably occur on rechallenge, and therapy should be discontinued. Difficulty with sleeping is a common tobacco withdrawal symptom. However, the patch itself may cause insomnia and abnormal dreams due to nicotine delivery at nighttime in smokers not used to nicotine during these hours. The administration of nicotine during waking hours only may be an effective means of dealing with this problem. Only one of the transdermal nicotine systems (Nicotrol) is approved for 16-hour usage, however. In contrast, some individuals report markedly improved sleep when using a 24-hour nicotine patch. These individuals are usually exceedingly heavy smokers with high nicotine dependence. It is possible that these individuals are undergoing nicotine withdrawal during the night, and their withdrawal symptoms contribute to their sleep disturbance. Nicotine replacement during bedtime hours may, therefore, treat a cause of their underlying insomnia.

It is generally recommended that transdermal nicotine systems be used in conjunction with behavioral modification programs. This is important because the transdermal nicotine may help reduce the intensity of nicotine withdrawal symptoms but does not address the behavioral aspects of smoking. Data suggest that nicotine replacement programs utilizing behavior modification result in higher long-term abstinence rates.[6] Nevertheless, even with minimal intervention, it appears that the transdermal nicotine delivery systems are associated with a therapeutic gain in smoking cessation rates.[15]

The possibility of nicotine replacement therapy contributing to cardiac events has been the subject of recent attention. In a direct study of 156 individuals with documented coronary artery disease, no difference in cardiac symptoms was observed between placebo and transdermal nicotine treatment groups.[12] Cardiac events are, unfortunately, common in the adult smoking population. The occurrence of fatal cardiac events, therefore, in individuals using nicotine replacement therapy for smoking cessation is not unexpected. Nevertheless, current recommendations are that individuals use nicotine replacement only as an aid to smoking cessation. Once using nicotine replacement, smokers should remain completely abstinent and should discontinue the use of their nicotine replacement if they relapse to smoking.

Recent attention has focused on potential hazards in smokers who use nicotine replacement but continue to smoke. These individuals have the possibility of increasing their total nicotine intake and, therefore, of becoming nicotine toxic. Interestingly, most smokers will adjust their nicotine intake if nicotine dosing is changed. For example, if supplemental nicotine is given, smokers have been observed to decrease their smoking.[1] In contrast, when smokers switch to low nicotine cigarettes, they tend to more efficiently extract the available nicotine.[16] In fact, while nicotine polacrilex gum has not been approved for such a use, some smok-

ers appear to be using it in order to cope with nicotine withdrawal symptoms while working or traveling in a smoke-free environment.[17]

Summary Comments

The nicotine transdermal systems appear to offer considerable advantages with regard to ease of use and patient acceptability. Nicotine polacrilex, while more difficult to use, allows the smoker some degree of control over nicotine dosing and may be more effective in individuals who experience social situations with particularly high risks for smoking relapse.

A number of important questions remain with regard to smoking cessation. First, the best weaning strategies to remove nicotine replacement from a smoker who has achieved abstinence have not yet been defined. It is generally recommended that full-dose therapy be continued for 2 to 6 weeks and that tapering be done in several stages of approximately 2 to 4 weeks each. It is likely that additional information on weaning strategies will be forthcoming in the near future. Whether combination therapy using nicotine replacement via transdermal systems in combination with nicotine polacrilex has advantages is also an area of current research interest. Finally, different dosing formulations are likely to become available.

In summary, smoking is a widespread addiction that is widely recognized to be dangerous. Quitting, however, is exceedingly difficult. Successful quitting involves a number of stages. The smoker must deal with loss of a source of pleasure, with changes in daily behaviors, and with nicotine withdrawal. Nicotine replacement therapy can help to minimize withdrawal symptoms. The option of having such therapy available either through nicotine polacrilex gum or through transdermal nicotine administration can provide a useful therapeutic option for individuals wishing to quit smoking.

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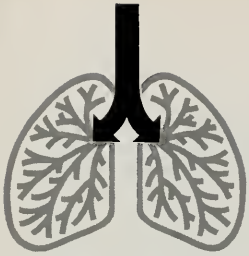

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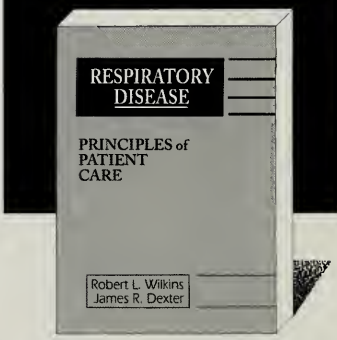

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Chronic Nasal Catarrh

In consequence of repeated attacks of acute catarrh, upper respiratory infection, or "cold in the head," as it is usually termed, the mucous membranes of the nose and the air-passages of the head become permanently thickened, the mucous follicles or glands, diseased, and their functions either destroyed or deranged.

In the early stages of the disease, the patient may be annoyed with "only a slight dropping into the throat," as many express it, the amount of the discharges from the air-passages of the head at this stage of the disease being only slightly in excess of health. In some cases the discharge is thick, ropy, and tough, requiring frequent and strong efforts in the way of blowing and spitting, to remove it from the throat, in which it frequently lodges. In other cases, or in other stages of the same case, the discharge is thin, watery, acrid, and profuse. The nose may be "stopped up" from the swollen and thickened condition of the lining mucous membrane, so as to necessitate respiration through the mouth, giving to the voice a disagreeable nasal twang. From the nature of the obstruction in this condition, it is useless for the sufferer to endeavor to clear the passage by blowing the nose; this only tends to render a bad matter worse, by increasing the irritation and swelling of the already thickened lining membrane. In some cases, the patient may suffer from headache a great portion of the time, which results in a confusion of his ideas. This renders him quite unfit for business, especially such as requires deep thought or mental labor. Memory may be more or less affected, and the disposition of those who are otherwise amiable, is often rendered irritable or morose and despondent. The mental faculties suffer to such an extent in some cases as to result in insanity. The sense of smell is in many cases impaired, and sometimes entirely lost, and the senses of taste and hearing are not unfrequently more or less affected.

The larynx, situated directly below the pharynx (throat), is subjected to the influence of the same irritation from acrid and poisonous discharges dropping into the throat from the head. More or less of it is removed by hawking and spitting, but some remains and is drawn into the larynx, or still lower into the trachea (windpipe), with the inspired air. Thus the disease creeps along the continuous mucous surfaces of the air-passages, the acrid, poisonous discharge arousing in its track the irritation, inflammation, ulceration, and thickening of the lining membrane which characterize the disease in other portions of the air-passages.

By the process of extension, the trachea and bronchial tubes, and lastly the parenchyma, or substance of the lungs, in their turn, become diseased, and bronchitis and consumption are firmly established. Tightness in the chest with difficulty of breathing; soreness; darting, sharp, dull, or heavy pain, or a distressing prickly sensation, accompanied with more or less expectoration—are evidences that the bronchial tubes have become affected, and the sufferer should be admonished that he is now standing on the stepping stone to consump-

This material is from "The People's Common Sense Medical Advisor, 53rd ed," which was published in 1895 by World's Dispensary Medical Association of Buffalo, New York, 1895: 474-5,479-84.

These excerpts were made available to RESPIRATORY CARE by Crystal L Dunlevy EdD RRT, Assistant Professor and Director of Clinical Education, Respiratory Therapy Division, School of Allied Medical Professions, The Ohio State University, Columbus, Ohio.

tion, over which thousands annually tread, in their slow journey to the grave.

Treatment—If you would remove an evil, strike at its root. As the predisposing or real cause of catarrh is, in the majority of cases, some weakness, impurity, or otherwise faulty condition of the system, in attempting to cure the disease our chief aim must be directed at removing the cause. The more we see of this odious disease, the more do we see the importance of combining with the use of a local, soothing, and healing application, a thorough and persistent internal use of blood-cleansing and tonic medicines.

As a local application for healing the diseased condition in the head, Dr. Sage's Catarrh Remedy is beyond all comparison, the best preparation ever invented. It is mild and pleasant to use, producing no smarting or pain, and containing no strong, irritating or caustic drug, or poison. Its ingredients are simple and harmless, yet when scientifically and skillfully combined in just the right proportions, they form a most wonderful and valuable healing medicine. Like gunpowder, which is formed of a combination of saltpeter, sulphur, and charcoal, the ingredients are simple, but the product of their combination is wonderful in its effects. The Remedy contains a powerful antiseptic, which speedily destroys all bad smell which accompanies so many cases of catarrh, thus affording great comfort to those who suffer from this disease.

In curing catarrh, and the various diseases which so frequently accompany it, such as throat, bronchial, and lung disease, the wonderful powers of the Remedy cannot be too strongly extolled. It has the specific effect upon the lining mucous membranes of the nasal and bronchial passages, promoting the natural secretion of their follicles and glands, thereby softening the diseased and thickened membrane, and restoring it to its natural thin, delicate, moist healthy condition. It is also unsurpassed as a blood purifier. When a cure is effected in this manner, it is permanent. The air-passages are so regulated, purified, and strengthened as to be strongly fortified against the encroachments of catarrh and other diseases. The effects of the Remedy on the system may be somewhat slow, and the alternative changes of tissue and function, gradual. Under the influence of Dr. Sage's Catarrh Remedy, all the secretions are aroused to carry the blood-poisons out of the system, and the patient finds himself gradually improving in flesh. His strength is built up, his lingering ailments dwindle away, and by and by he finds his whole person has been entirely renovated and repaired. He feels like a new man—a perfect being.

As is widely known with consumption, the diet has an important influence on this disease. Fat meats, rich sweet cream, good butter, and other similar articles of food, should comprise the diet. These elements, which are prolific in the production of animal heat, counteract the predisposition to take cold.

Caution on the time required in effecting a cure—Reader, if you suffer from chronic nasal catarrh and its odious complications, do not expect to be very speedily cured, especially if your case is one of long standing. Unprincipled quacks and charlatans, who possess no knowledge of disease, or medicine either, and whose sole design is to palm off upon you a bottle or two of some worse than worthless strong, caustic solution, irritating snuff, or drying fumigator, or other strong preparation, will tell you that even the worst cases can be speedily cured by these unreasonable means. It is true that such strong, irritating, and drying preparations will, many times, suddenly arrest the discharge from the nose, but the thickened and ulcerated condition of the lining mucous membrane, which really constitutes the disease, is not removed by such treatment, and the discharge soon comes on again. Besides, there is danger attending the employment

of such preparations. The disease, by their use, is frequently driven to the throat, bronchial tubes, lungs, or brain, and thus a bad matter is made worse. Not less irrational and unsuccessful is the plan of treating the disease with inhalations of drugs or preparations through variously-devised pocket and other inhalers (see Fig. 10 and 11). Such treatment may mask the catarrh for a time, but, by reason of

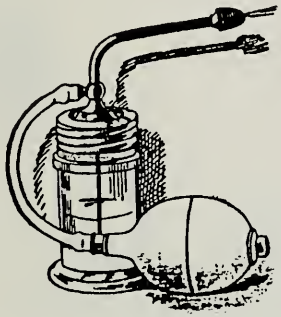

Fig. 10. Atomizer.

the constitutional nature of the disease, it cannot effect a perfect or permanent cure. Dr. Sage's Catarrh Remedy, on the other hand, cures the disease on common-sense, rational, and scientific principles by its mild, soothing, and healing properties,

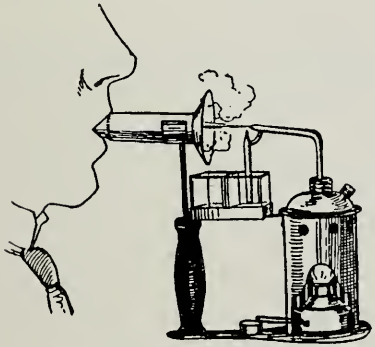

Fig. 11. Steam atomizer illustrating position of head during treatment.

to which the disease gradually yields, when the system has been put in perfect order. This is the only perfectly safe, scientific, and successful mode of acting upon and healing it. Without, we trust, being considered egotistical, we can say that this opinion is based upon a large experience and a perfect familiarity with the nature and curability of the disease. Cases of catarrh have been treated by thousands, and our medicine for the cure of this loathsome disease, have met with an extensive sale in all parts of these United States, and have found their way into many foreign countries. The universal satisfaction with which their use has been attended, and the grateful manifestations received from the cured, have afforded one of the greatest pleasures of our lives. Scarcely a mail arrives that does not bring new testimony of cures effected by the treatment here recommended.

Direction for using Dr. Sage's Catarrh Remedy—To prepare the medicine ready for use, put the whole quantity of powder contained in the package, as put up for sale, into a bottle; pour it into one pint of cool, soft water. Rain water or melted snow is good. Ordinary lake, river, well, or spring water will do if only slightly hard. Cork the bottle tightly and shake it thoroughly, after which allow it to stand six or eight hours to settle. Two of the ingredients of which the Remedy is composed do not entirely dissolve, but their medicinal properties are completely and speedily extracted and taken up by the water. These settlings have lost their medicinal properties and should not be allowed to enter the nasal cavity. It should be kept tightly corked, not allowed to freeze in winter, or be kept where it is very warm in summer. This is now termed "Catarrh Remedy Fluid."

Use the fluid, prepared according to the above preparation, not less than three or four times a day, the last time just before retiring, in the following manner: Without shaking the bottle to roll the fluid, pour

out a teaspoonful or more into the hollow of the hand, hold it there until warmed; first gently, and afterwards forcibly, snuff the fluid up one nostril and then the other, until the nose is well filled, and it passes back into the throat. No fears need be entertained that it will produce strangling or any unpleasant effect in thus using it, unlike any other fluids, it does not produce the slightest pain or disagreeable feeling, but, on the contrary, leaves such a cooling, pleasant sensation that its use soon becomes a pleasure rather than a task. In a few minutes after thus using the remedy, it should be blown out gently (never forcibly), to clear the nose and throat of all hardened crusts and offensive accumulations, if any such exist. This process should be repeated until the Remedy has been thoroughly applied two or three times, not blowing it out the last time of using it, but retaining the medicine in contact with the affected parts for a considerable length of time. No harm can result if the fluid be swallowed, as it contains nothing poisonous or injurious.

A Better Way—The manner of using Dr. Sage's Catarrh Remedy, advised above, is somewhat imperfect and not nearly so thorough a mode as the one to which the reader's attention will now be directed.

In a very large number of bad cases of catarrh, or those of long standing with bronchial complications, the disease has crept along and extended high up into the nasal passages, and into the various cavities and tubes communicating therewith. The act of snuffing the fluid carries it along the floor of the nose and into the throat, but does not carry it far enough to reach all of the chambers, tubes, and surfaces that are affected with the disease.

Now, in order to be most successful in the treatment of catarrh, it is necessary that the remedy should reach and be thoroughly applied to all affected parts. This can be accomplished in only one way, which is by hydrostatic pressure. The anatomy of the nasal passages, and the various chambers and tubes that communicate therewith, is such that they cannot be reached with fluid administered with any kind of syringe, or inhaler, or instrument, except one constructed to apply it upon the principle above stated. Such an instrument is Dr. Pierce's Nasal Douche (Fig. 12). By the use of this instrument, the fluid enters every portion of the air-passages, no snuffing being required.

Fig. 12. This cut illustrates the manner of using Dr. Pierce's Nasal Douche.

Directions for using Dr. Sage's Catarrh Remedy with this instrument—Put the reservoir on a shelf, or hang it up, so that it will be a little higher than the head; fill the reservoir with salt and water pressing the tube between the thumb and forefinger so as to prevent the fluid from escaping through it; introduce the nozzle at the end of the tube into one nostril, pressing it in far enough to close the entrance of the passage so that no fluid can escape by the side of the tube, breathe through the mouth, avoid swallowing, and allow the fluid to flow. The soft palate, by the act of

breathing through the mouth, is elevated, so as to completely close the passage into the throat, and thus the fluid is made to flow up one nostril in a gentle stream, to pass into and thoroughly cleanse all the cavities connected with the nasal passages, and to flow out of the other nostril. The douche should not be employed unless both nostrils are open and the flow is free. Do not forget that the instrument will not work properly unless you breathe through the mouth and avoid swallowing while the fluid flows.

Fill the reservoir a second time with the simple salt and water, and, inserting the nozzle into the nostril out of which the fluid flowed on using it the first time, pass the current through in the opposite direction; that is, so that it will flow out of the nostril into which it flowed the first time using it.

After having thus thoroughly cleansed the passages, fill the instrument half full or more with the "Catarrh Remedy Fluid" prepared as heretofore directed, and warmed to a moderate temperature, and pass this through the nose in the same manner as directed for the salt water.

Let no one entertain any feeling of timidity on commencing the use of this instrument, as its operation is perfectly simple and harmless, and, with the fluids which we recommend, is never attended with any strangling, choking, pain, or other disagreeable sensations. The medicine should be applied with the Douche at least twice a day, in the morning, and at night on retiring. There is no advantage of using the medicine oftener than three times a day, when used with the instrument, but a sufficient quantity should be used each time to medicate all of the diseased parts. If any remains in the Douche, it may be poured back into the stock solution for subsequent use, but a liquid that has once passed through the nasal cavity contains the germs of the catarrh, and must not be used a second time.

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A Sea of Air

One of the puzzles in the early part of the seventeenth century was that a suction pump could not raise water higher than 34 feet. Galileo in his "Dialogues Concerning Two New Sciences" has one of his characters say, "I once saw a cistern which had been provided with a pump under the mistaken impression that the water might thus be drawn with less effort or in greater quantity than by means of the ordinary bucket . . .. This pump worked perfectly so long as the water in the cistern stood above a certain level; but below this level the pump failed to work. When I first noted this phenomenon, I thought the machine was out of order; but the workman whom I called to repair it told me the defect was not in the pump but in the water, which had fallen too low to be raised to such a height; and he added that it was not possible, either by a pump or by any other machine working on the principle of attraction, to lift water a hair's breadth above eighteen cubits."[1] (A cubit, an ancient measure of length, was the length of the forearm, or cubitus, from the tip of the middle finger to the elbow. In the Scriptures, this distance was about 22 inches; later, it became 18 inches.)

We know now that, at sea level, the atmosphere presses down with a weight equivalent to that of a column of mercury about 30 inches high. Since mercury is almost 13.6 times as heavy as water, the weight of air, if unopposed, can support a column of water 406 inches, or about 18 cubits, high. Whenever the pressure of air is decreased above a segment of water (as by sucking on a straw immersed in water), the water rises in it; if a good vacuum pump replaces inspiratory effort, and creates a near-vacuum in the tube, the water will rise to almost 34 feet, but no higher.

Galileo knew of the problem of pumping water but apparently did not concern himself with it. However, his pupil, Evangelista Torricelli, did. There were few scientific publications in 1644 and Torricelli told of his experiments in a letter to Cardinal Ricci—so one can only surmise that his famous experiment was related to the practical problem of pumping water.[2] Torricelli obviously could not experiment with a glass tube 18 cubits high but he could with one 1/14 as high. This solution was an elegantly simple one; he made the *contents* of a short tube 14 times as heavy by substituting mercury for water. Using a glass tube 2 cubits long and closed at one end, he filled it with mercury, stoppered the upper, open end with his finger, and inverted it in a basin of mercury (Figure 1). When he removed his finger, the mercury column dropped to "a height of a cubit and a quarter and an inch besides" (29.75 inches, if we assume that Torricelli's cubit was 23 inches).[2] In this one series of experiments, Torricelli made four important contributions. (1) He developed an entirely new concept—"that we live submerged at the bottom of a sea of the element air, which by unquestioned experiments is known to have weight." (2) He invented the barometer, a scientific instrument for measuring the weight of the air. (3) He produced in his tube *above* the mercury column what came to be known as a Torricellian vacuum. (4) He opened the door for quantitative measurements in "pneumatics" and a renaissance in physics.

The first consequence of Torricelli's discovery provided the basis for high altitude physiology. In 1648, Pascal reasoned that, if air did indeed have weight, it must have less weight on a mountain top than at sea level; this his brother-in-law, Perier, confirmed—though with such exact data that some suspect he *calculated* the pressure rather than measured it!

The second consequence was Boyle's reasoning that if air pressing on the mercury in the dish supported the mercury in the tube, the mercury column should fall if he enclosed the dish and sucked out air above the mercury. This led to a continuing

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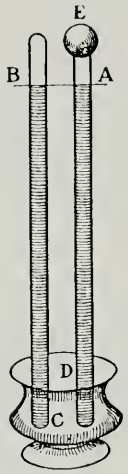

Fig. 1. Torricelli's barometer.[2]

series of experiments by Boyle with ever-improved suction pumps and to the birth of experimental, quantitative physics, supported by published measurements. Boyle in 1669 constructed a U-tube with a short leg closed at the top and a long leg open at the top into which he could pour mercury. When he increased the height of the column of mercury from 29 2/16 inches to 58 13/16 inches, the volume of air trapped above the mercury in the short leg decreased from 48 units to 24 units and Boyle's law was born.[3] Boyle also developed improved suction pumps to replace the Torricellian vacuum and evacuated glass chambers to learn that sound required air for its transmission. (Boyle's pumps probably were unable to lower pressures to less than 1/4 inch of mercury because he lacked modern equipment for making leak-proof seals for moving parts. It was not until an important industrial need arose for lower pressures that modern pumps were developed; the need came in the 1880s when Edison was developing the incandescent lamp.[1])

For certain advances, the new physics had to await the new chemistry in the eighteenth century—and the new physiology in the nineteenth. Dalton's law of partial pressure (1805) and his atomic theory,[4] built initially on studies of gases, required the discoveries of CO_2 by Black in 1755[5] and of O_2 by Lavoisier in 1776[6] because these provided proof that air was composed of several elements. Poiseuille's study of cardiovascular physiology, and especially of resistance to flow through both large and very fine tubes, led him in 1828 to construct a U-tube open at both ends, fill it part way with mercury, and use it to record superimposed blood pressure; in 1847, Ludwig added a float with a stylus to write on a rotating kymograph and created the first system to record dynamic cardiovascular events. Mountain sickness and disasters in balloons at high altitudes led Paul Bert to his classic studies in high and low pressure chambers recorded in his monograph "La Pression Barométrique" in 1878.[7]

A few years ago, engineers, wanting a more convenient term than "millimeters of mercury" (8 syllables), hit upon a one-syllable contraction of Torricelli—"torr." One torr is essentially the pressure required to support a column of mercury 1 mm high when the mercury is of standard density and subject to standard acceleration. Torr is now used by many respiratory physiologists in referring to total and partial gas pressures and serves the double purpose of simplifying speech and honoring the Italian physicist who first measured the weight of the sea of air whose bottom we inhabit.

It is true that Torricelli's experiments were built on the older science of hydrostatics and the knowledge that the pressure at the bottom of a vessel filled with water depended on the *height* of the water and not on the volume or shape of the vessel. But to paraphrase Albert Szent Gyorgi (in his definition of creative research), Torricelli looked at what everyone had looked at before, saw what everyone had seen before, but *thought* what no one else had thought before.

Julius H. Comroe, Jr.

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Pocket Companion of Critical Care: Immediate Concerns, edited by Robert R Kirby MD, Robert W Taylor MD, and Joseph M Civetta MD. Soft-cover, illustrated, 760 pages. Philadelphia: JB Lippincott, 1990. $44.95.

This book is a reformatting of the excellent textbook, **Critical Care** (Philadelphia: JB Lippincott, 1988) edited by the same three authors. Each of these authors is a well-known clinician in medicine, surgery, and/or anesthesiology, and together they have compiled a textbook that I believe is one of the leading textbooks in the field of critical care. The original comprehensive textbook (1,700 pages, 166 contributors) covers virtually every topic in critical care medicine and surgery but is too large to be useful on an hour-to-hour basis in a busy ICU. These three editors, realizing the limitations of their exhaustive textbook, have reworked the contributions by the impressive array of contributors and have produced this "pocket companion" containing the information that is crucial in caring for a patient during his or her initial 24-48 hours in an ICU. To fully appreciate the job these editors have done, one should read the comprehensive textbook and then read the **Pocket Companion.** They have successfully distilled the nearly 2,000 pages of the full-sized textbook into a notable soft-cover book of fewer than 800 pages.

According to the authors, the **Pocket Companion** was written for both the neophyte and the seasoned practitioner (defined as "physician, nurse, respiratory therapist, or other health care provider"). Unfortunately, this wide gamut of intended audience cannot be served by a single book unless the more experienced practitioner frequently refers to the comprehensive textbook or bibliography, while the inexperienced practitioner reads strictly for information on a specific diagnosis and not for an understanding of the disease process. With this single caveat in mind, I say that the authors have done an excellent job in producing a book that is logical in its approach to medical and surgical disorders, covers the fundamental areas of ICU practice in a clear and concise fashion (especially that information that is crucial in the first 24 hours of a patient's care), and, most importantly, refers the reader to the relevant chapter in their comprehensive textbook.

The **Pocket Companion** itself is divided into 16 sections and further subdivided into 94 chapters, thus making it easy to access information and formulate a management plan. The first section deals with fundamental considerations in the care of all ICU patients—the clinical assessment, fluid and electrolytes, and nutrition, for example. The next two sections cover surgical, gynecologic, and obstetric patients and the specific disorders associated with these groups of ICU patients. The middle nine sections use a systematic approach to ICU disorders to cover most of the relevant diseases seen in ICU patients. The sections of Neurologic/Psychiatric Disorders and Gastrointestinal Disorders are especially well written and should be extremely useful to health care practitioners. The clinical expertise and practicality of the authors is evident from the manner in which these nine sections are written. The final four sections of the book cover ICU Infections, Environmental Hazards, Organ Transplantation, and Resuscitation (which includes two concise chapters on whom to resuscitate and when to stop resuscitation efforts). The index, which is frequently the weakest part of a compiled book, is excellent for locating topics relevant to a specific diagnosis.

Pocket Companion of Critical Care: Immediate Concerns is easy to read and understand. I had the pleasure of reading and using the book during a month of attending in a medical ICU and believe that the book is best suited for the health care practitioner who needs to have a core knowledge of a specific diagnosis, such as postabortal infections or tubo-ovarian abscess, and not for residents and nurses who need a more detailed and comprehensive understanding of their patient's disease process(es).

Overall, the **Pocket Companion of Critical Care: Immediate Concerns** is a useful source of information furnished by three well-respected editors. Although it cannot replace their comprehensive textbook on critical care (now in its second edition), it does offer a convenient pocket-sized reference. I have recommended that this book be added to the nursing staff's library in our medical and coronary ICU, not so much for their use, but for use by nursing students, respiratory therapy students, and those health care practitioners rotating through our unit and seeing ICU patients for the first time who need a quick and easily read body of information relevant to a patient's specific diagnosis and initial care.

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Manual of Pulmonary Function Testing, 5th ed, by Gregg Ruppel MEd RRT. Softcover, 94 illustrations, 409 pages. St Louis: Mosby-Year Book Inc, 1991. $29.95.

It has been 16 years since the first edition of this familiar manual was published. The manual—now in its fifth edition—has established itself as a standard for the instruction of pulmonary function (PF) testing. Since the first edition, its content has been expanded to reflect advances in the practice and sophistication of PF testing. From its original 105 pages with 42 illustrations, the manual has grown to 94 illustrations in 409 pages. Nevertheless, the manual's general format has remained unchanged over the years, in that it continues to describe PF testing on a test-by-test basis.

The manual has become a commonly used text in training programs that include PF testing in their curriculum. A recent informal survey of directors of respiratory care programs found that more than 80% of the respondents used this manual in their programs (personal communication from participant, Duane Peterson, Program Director, St Paul Technical College, St Paul, Minnesota, 1992). The text identifies, describes, and discusses the significance of all commonly ordered PF tests and covers most tests performed in specialized or research laboratories. The manual links the equipment necessary to perform each diagnostic test to the test itself, often with accompanying illustrations of the equipment—perhaps a unique feature. It also details how to properly perform each test to obtain acceptable results. Complete descriptions of tests are often supported by illustrations, equations, and tables. The descriptions of tests performed rarely or in specialized laboratories allow instruction in and understanding of aspects of pulmonary pathophysiology. Well-designed self-assessment questions at the end of each chapter allow readers and instructors to obtain feedback on understanding of concepts presented.

The manual is not intended to serve all purposes. This is not a deficiency of the manual but is mentioned as a caveat, or cautionary note, to the potential reader. The manual is not a stand-alone 'how-to' or procedure manual for performing PF tests. It may properly precede clinical instruction but not substitute for it. It also cannot be used to instruct on the pathophysiology of lung disease but may be used to complement such instruction. Finally, the manual is not a critical review of the merits of pulmonary function tests. The text is not referenced—although a selected bibliography is provided at the end of each chapter to direct readers to further information on the tests discussed in that chapter.

Compared with the fourth edition, the fifth edition of the manual now contains more general information on PF monitoring and measurements in the critical care setting. The more recent edition has added sections on mixed venous oxygen saturation monitoring, capnography, pulse oximetry, and indirect calorimetry. It has also expanded the sections on O_2- and CO_2-response testing, while adding sections on infection control and the 1987 American Thoracic Society (ATS) Standards for acceptable spirometry.[1] A relatively minor point, but one worth mentioning, is that the ATS standards for volume accuracy and flow resistance are cited inconsistently in the text on Pages 183 and 295 and in the table on Page 293. The table displays the correct standards.[1] I feel certain that this error will be corrected in the projected sixth edition. Although the chapter on computers in the PF lab has been expanded, I believe it continues to require more background on computing and linkage to PF testing with examples (an expansion that the author may believe to be beyond the book's scope).

The manual is written in an understandable manner and is well edited. When I evaluated several sections with Rightwriter (a software program for measuring readability), I found the manual to be written at a 14th grade level, appropriate for college-level instruction. It contains a considerable amount of jargon specific to medicine and respiratory disease, and, therefore, may not be suitable for a beginning student or one unfamiliar with the terminology of respiratory care.

Ruppel continues to update and improve upon previous editions. For the purposes stated above, I believe it to be the best manual of its kind. This manual can be strongly recommended for students of PF testing or as a reference for those practicing PF testing.

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Atlas of the Difficult Airway, by Martin L Norton MSPH MD JD DAn and Allan CD Brown MB ChB. Hardcover, illustrated, 225 pages. St Louis: Mosby-Year Book Inc, 1991. $60.00.

The authors of this book possess considerable expertise on the management of difficult airways, and the book is a valuable source of information because it provides firsthand accounts of the authors' experiences with patients in the Difficult Airway Clinic of the Department of Anes-

thesiology at the University of Michigan Hospitals. This publication is intended for physicians, nurses, medical students, respiratory therapists, and other health care professionals familiar with airway management.

The book is organized into three parts in a concise and logical manner. Part I includes Chapters 1-3, in which the authors describe the instruments used in and normal practices of intubation. The text further explains and illustrates several pieces of equipment used in managing difficult airways. Chapter 4 provides a descriptive account of the valuable work being done at the Difficult Airway Clinic. In Part II, Chapters 5 and 6 reacquaint the reader with the anatomy and physiology of the craniofacial area and Chapters 6-8 specify some methods that are currently utilized for airway evaluation. In Part III, the reader encounters actual illustrations of difficult airways. Chapters in this section include problems with bony and soft tissue abnormalities, obesity, burns, oral and maxillofacial abnormalities, and pediatric patients. Each problem is thoroughly discussed.

The illustrations in this book are graphic, which probably explains the term "atlas." These pictorials are important because they allow the reader a better understanding of the degree of difficulty each airway presents. An additional merit of the book is that not only does it point out different types of difficult airways, but it also delivers reliable suggestions for management of patients with the anomalies described. Furthermore, an appendix is included for quick reference to specific subjects.

The **Atlas of the Difficult Airway** successfully steers its intended readers toward a better understanding of the management of difficult airways. The authors' extensive knowledge of the subject helps focus the reader's attention on possible modalities to pursue in managing these types of patients. This book would be a valuable source of information for the prospective intubationist because it is written as a guide to allow the intubationist to proceed with a better knowledge of the diversified airways he/she might encounter in his/her years of practice.

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SleepLab 4.56, by CNS Inc, 1250 Park Road, Chanhassen MN 55317. (612) 474-7600. Six 5-1/4″ floppy diskettes supporting SleepLab™ 2000 MS-DOS computer-based sleep disorders recording system (an integral part of the SleepLab system).

It has been said that a camel is a horse that was designed by a committee: a wonderfully durable animal, capable of carrying great burdens over long distances at fair speeds and requiring minimal care. These sterling characteristics are offset by a contrary disposition, malevolent temperament, unattractive features, and bad breath.

I am reminded of a camel every time I use the latest version of SleepLab software to set up, stage, score, and report nocturnal polysomnograms (NPSG) from our laboratory—170 studies as of this review. The software has an ad hoc feel about it. Its 100+ component parts (files) appear to have been developed by different programmers but compiled by some omnipotent presence molding them into a powerful, yet awkward, whole.

The system boots-up to a very pleasing main menu that features, besides four menu options, a nice analog clock with a sweep second hand. The user is prompted to press the number corresponding to the option desired: 1-Polygraph, 2-Analysis, 3-Utilities, or 4-Exit to DOS.

A new case is initialized by selecting 1-Polygraph. After about 20 seconds the Record submenu appears. The user is now prompted to use function (F) keys instead of number keys to continue. Pressing F1-Case brings up the Form Editing screen that is, without question, one of the most awkward, frustrating, arcane software components that I have ever tried to master!

Digressing at this point, I speculate that users with minimal personal computer (PC) experience probably would not be as annoyed with this software module as I am. On the other hand, it is a torment to touch typists and PC mavens who are accustomed to the same conventions being used throughout multiple layers of sophisticated software.

For example, the following data are entered during the Form Editing process but for some extraordinary reason never appear on any of the reports generated: room number, physician's name, polysomnographer's name, or comments! There should be space for the names of two physicians—the referring one and the one interpreting the NPSG; and both names should appear on all reports and supporting documents. Further, what good does entering "CPAP titration" as a comment when it never appears anywhere except on the monitor?

Quirks and comedy are present during the Form Editing exercise. One cannot use ASCII character 47, "/," when entering the patient's date of birth. Character 45, "–," must be used even though on the very next line the software generated test date appears with slashes, "/."

Recently an optical disk failure occurred about 270 minutes into a sleep study. Not having experienced this particular phenomenon before, I took some moments to puzzle through a strategy for handling the problem. I sequentially terminated the current study, inserted a new op-

tical disk, reentered the Form Editing data, and started a new study. In the meantime, the patient entered Stage REM (rapid eye movement) sleep. Our SleepLab 2000 system uses external amplifiers of a polygraph machine so, despite the interruption, Stage REM data were being captured on paper. The end result was that even though this was a single study, it was necessary to present the interpreting physician with three different data sets. Had there been a convenient way to capture the original Form Editing information, especially the test number, the interruption would have been seconds rather than 6 minutes.

The Edit/Print Events segment of the Analysis menu is limited only by the user's ability to recognize and describe events in 20 characters or less. Unfortunately, the software version available in our laboratory does not support a cursor on the monitor. With nearly every NPSG I analyze, I find myself having to backspace (one cannot scroll back without a cursor) on the keyboard to correct misentries. I speculate that the programmer of this module failed to recognize how important a cursor is to a touch-typist using a PC monitor.

The statement, "This is displayed only when an event is detected ...," appears in red on the monitor during the Spontaneous Arousal portion of NPSG Analysis. What does this troubling and mysterious statement mean? What events are being detected: periodic leg movements (PLMS), apneas, hypopneas, or arousals? Why does this statement NOT appear on the screen during the PLMS and Arousals or the Apnea and Arousals segments of analysis? Why is the statement even displayed since Spontaneous Arousal analysis requires no user intervention?

In an earlier version of SleepLab software, two very convenient, useful function keys were available on the option bar during the NPSG. They were F9-Out Bed followed by F1-In Bed. During the first NPSG following the installation of the latest software upgrade, I reached for the F9 key as a matter of habit when my patient needed to get out of bed. Nothing happened! That event option was no longer available. I was fearful that I had improperly installed the upgrade, imagining all sorts of horrible consequences. Middle-of-the-night panic calls to CNS headquarters and to my representative revealed that these functions were no longer supported. I was casually instructed to include them in my Edit/Print Event Descriptions utility.

In my judgment, this was a meaningful software modification, albeit a surface one. It should have been accompanied by a change notice or some form of advance explanation. More importantly, this small event has raised questions in my mind about customer support and customer relations by CNS Inc.

Like the camel, **SleepLab 4.56** is a powerful beast. Its Utilities component gives the user exquisitely fine control over data parameters, data acquisition parameters, montage creation, and waveform parameters—all essential for a paperless laboratory. It can generate up to 36 attractive, easily understood reports, graphs, and histograms in black-and-white print or in color. It can reputedly store up to 30 complete studies on one WORM (write once, read many) optical disk, although we average about 17 cases per disk. It can 'play-back' raw data to a standard polygraph machine. Its central processing unit (CPU) footprint, with internal amplifiers, requires only a third as much floor space as does a conventional polygraph device.

My criticism is one of form, not substance. SleepLab 2000 has served this institution well. However, potential users of the system, especially those who have familiarity with complex computer-assisted design (CAD) programs, the latest generation of word-processors, standard graphics interface systems, or popular desktop publishing software, will find the SleepLab 'ride' to be a bit bumpy. I sense that if CNS programmers applied the same degree of imagination and thought to the Polygraph component as they obviously did to Analysis and Utilities, those glimmers of elegance that one sees would break through. Streamlining the program code coupled with better after-sale customer relations, and, perhaps, expanded field testing, should result in a superior user-friendly product.

Despite my criticism, I can recommend this package (1) to existing laboratories thinking about making theirs a paperless one, and (2) to new operations needing a sophisticated tool to help with NPSG scoring, staging, and report generating.

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Letters

Objections to Home Oxygen CPG

As a registered respiratory therapist involved in home care for the last 8 years, I welcome the AARC's efforts to set forth Clinical Practice Guidelines for respiratory care in the home. However, I do have several concerns with the "Clinical Practice Guidelines for Oxygen Therapy in the Home or Extended Care Facility"[1] as they appeared in the August 1992 issue of the Journal.

Section 10.2 Personnel: Credentialed respiratory care practitioners (RRT or CRTT) or other credentialed persons with equivalent training and documented ability to perform the tasks may assess patients, initiate and monitor oxygen delivery systems, recommend changes in therapy, and instruct caregivers.

In my opinion, this AARC mandate is not practical, feasible, or for that matter necessary in the home setting. As I am sure you are aware, it is common for reputable durable medical equipment (DME) companies to use trained, non-credentialed service technicians to set up and monitor the function of oxygen equipment in the home. Respiratory therapists and other paraprofessionals then contact the patient to assess the home environment and the patient's condition. The therapist may recommend any necessary changes in therapy to the patient's physician. To my knowledge, there is no valid research to indicate that current teaching practices by home medical equipment (HME) suppliers are ineffective. (May I remind the committee members that oxygen is not necessarily initiated by credentialed personnel in the hospital setting either.)

I am curious to know why those formulating the Clinical Practice Guidelines for Home Oxygen Therapy feel that only credentialed personnel should initiate oxygen in the home. JCAHO does not require HMEs to provide this level of personnel to initiate oxygen service. The JCAHO standard simply requires the individual be trained.

In a world of budget deficits and reimbursement cuts, HME suppliers cannot afford to meet such standards as recommended by the AARC. As we all know, respiratory care is not a recognized reimbursable service in the home, and I respectfully suggest that your stringent recommendations may force patients to relinquish services already available, without hope of a practical alternative. I do believe HME suppliers should employ credentialed respiratory therapists. However, respiratory care should be available to patients based on their identified needs—determined through an evaluation of their home environments and their physical conditions.

Section OT-CC 11.0 Monitoring: . . . Patients should be visited/monitored at least once a month by credentialed personnel unless conditions warrant more frequent visits.

I agree that every home oxygen patient should be initially monitored to assess his or her condition and home environment (by a therapist or trained individual working under the jurisdiction of a therapist). I *do not* agree, however, that all home oxygen patients require monthly follow-up. The ongoing care of any patient should be based on *need*, through the professional judgment of a therapist in consultation with the patient's physician. Some patients may indeed require biweekly contacts, whereas others may need less frequent visits.

Numerous oxygen modalities do require periodic checks and maintenance to assure adequate function in the home. For example, concentrator manufacturers provide maintenance recommendations for each model. These functional maintenance checks can be performed by any of a number of *trained* individuals, (not necessarily therapists) in the home. Reputable HME dealers must follow such manufacturer's recommendations for equipment safety purposes. Let's remember health care must be cost-effective!

Section OT-CC 11.2: Equipment Maintenance & Supervision: . . . A respiratory care practitioner or equivalent should during monthly visits reinforce appropriate practices and performance by the patient and caregivers and assure that the oxygen equipment is being maintained in accordance with manufacturers' recommendations.

All patients and caregivers alike need continual reinforcement regarding the use of their home medical equipment. This reinforcement can be provided through the service technicians filling the oxygen reservoirs, associated nursing agencies, and the credentialed therapist employed by the HME supplier. In addition, equipment maintenance should be provided according to manufacturer specifications, using trained individuals. Ongoing instruction regarding the use of the equipment should be based on the individual patient's need.

As we take our profession into the 21st century, we must recognize the therapist's role in the home care industry. As long as respiratory care is not a reimbursable service in the home, reputable HMEs must provide care (just as we do in the hospitals) where it is *needed*—to patients with poor environments and changing medical conditions.

Once again, I applaud the AARC's efforts to address respiratory home care. At the same time I caution you to evaluate the practical implementation of any suggested home care guidelines. Thank you for the opportunity to voice my opinion.

Lynn Fegley Meadows RRT CPFT
Pittsburgh District Manager
Homedco
Pittsburgh, Pennsylvania

REFERENCES

1. American Association for Respiratory Care. Clinical practice guideline: oxygen therapy in the home or extended care facility. Respir Care 1992;37:918-922.

Ms Lewis responds:

First, let me review what the Guideline in question—and all AARC Guidelines—are and are not.[1] They are clinical, practical, profession-oriented, voluntary, and evolving. They are not procedures. They are not hypothetical, theoretical, institution-oriented or institution-specific, regulatory, or static.

"Oxygen Therapy in the Home and Extended Care Facility"[2] went through 7 drafts and was reviewed by the Steering Committee and the Review Panel of more than 600 members. All responses substantiated by published references—both additions and objections—were incorporated into the final draft before the Guideline was released for publication. The reviewers included persons representing home care organizations and durable medical equipment vendors (DMEs).

With these points in mind, let me respond to your inquiries. First, we did not "mandate" anything. As members of the Committee developed the Guideline, we considered who should perform the procedures. Site neutrality was upheld. In our first Guideline "Oxygen Therapy in the Acute Care Hospital,"[3] we had recommended a credentialed respiratory care practitioner or the equivalent. We believe that the recommendation holds for the home and extended care facility. The assurance of quality care is uppermost.

The issue of monitoring was thoroughly discussed. Before completion of the Guidelines, a member of the team contacted a number of DME representatives for input concerning monitoring. The Guideline specifies that the patient and the equipment be evaluated "at least once a month" and does not preclude more frequent evaluation when indicated. For patients believed to need less frequent visits, the burden of proof that monitoring and evaluation are adequate lies with the organization. The Committee believes that patient evaluation by a qualified practitioner is essential and that the concurrent provision of equipment monitoring by that practitioner can constitute the most fiscally responsible and cost-effective approach.

Cost-effectiveness is important but it must be coupled with the foremost consideration—quality patient care. As the respiratory care profession expands the care settings in which we practice, the AARC continues to work for reimbursement for services outside the acute care hospital. As health care reform is debated in Washington, the AARC is working to have respiratory care participation specified in every bill.

From the inception of the CPG project, the door has been open to all those interested—caregivers in hospitals, homes, and skilled nursing facilities; managers; administrators; agency officials; physicians; nurses—to join the Review Panel to provide critique and comment. That invitation has been extended by personal contact, letter, word-of-mouth, *AARC Times* notices, and most recently in the February issue of the Journal.[4] We would welcome your participation. Thus, as new Guidelines are developed you would have an avenue for input prior to final draft and publication.

Thank you for your letter. Your thoughtful comments (and those of other interested persons) can only help make each Guideline better.

Dianne Lewis MS RRT
Chairman
Oxygen Therapy Guidelines
Committee
Naples, Florida

REFERENCES

1. Hess D. The AARC clinical practice guidelines. Respir Care 1991; 36:1398-1401.
2. American Association for Respiratory Care. Clinical practice guideline: oxygen therapy in the home or extended care facility. Respir Care 1992;37:918-922.
3. American Association for Respiratory Care. Clinical practice guideline: oxygen therapy in the acute care hospital. Respir Care 1991;36: 1410-1413.
4. Brougher P. A call to participate—clinical practice guidelines (editorial). Respir Care 1993;38:181-182.

Nonconventional Ribavirin Administration, via Incubator

As respiratory care practitioners we possess knowledge of state-of-the-art medical advances. We rely on meticulously conducted research to guide us clinically to avoid that worst-case scenario "You want me to try to do what???" I was recently faced with such a challenge when asked to initiate ribavirin therapy—a relatively simple request. However, in this case that simple request was complicated by a hypothermic infant and the lack of an overbed warmer or open incubator.

My dilemma arose when a 14-day-old infant with Downs Syndrome was diagnosed with respiratory syncytial virus (RSV) by two sequential nasal washings positive for RSV by ELISA viral identification test, and the attending physician ordered ribavirin therapy. On admission, the infant had been placed in 35% oxygen via oxygen hood, with the gas mixture heated to the upper limit of thermal neutrality. Pulse oximetry was utilized to monitor the infant's oxygenation status and F_{IO_2} adjustments were made to maintain an S_{aO_2} greater than 92%. The infant had been swaddled and placed on a warmer pad to increase body temperature, but all efforts failed to resolve the hypothermia. The infant was then placed in a conventional incubator (Airshield's C100 Isolette) because no overbed warmer was available. A heated passover humidification system, utilizing a Fisher-Paykel heater and prepackaged, disposable 72-inch heated-wire tubing, inserted through a port hole proximal to the patient, delivered and maintained the prescribed F_{IO_2} at a flow-rate of 16 L/min. Port hole sleeves were inserted on all port holes on the incubator to minimize heat loss and F_{IO_2} fluctuation when access to the infant was necessary. An oxygen analyzer was placed within the incubator to continuously monitor the F_{IO_2}. Alarm limits were set at ±2% of the prescribed F_{IO_2} to ensure the accuracy of oxygen delivery. The size of the infant and limited accessibility prevented the use of a hood within the incubator.

In my quest for knowledge, I discovered extensive research substantiating the safe and effective use of ribavirin therapy for the treatment of RSV. These noteworthy contributions describe the use of oxygen hoods and face masks for administering this drug to the nonintubated pediatric patient, but I searched and found nothing about delivering ribavirin in an incubator.

Overbed warmers are expensive and not always readily available, as I found out. It was critical that I find equipment capable of performing the dual function of maintaining an acceptable body temperature and pro-

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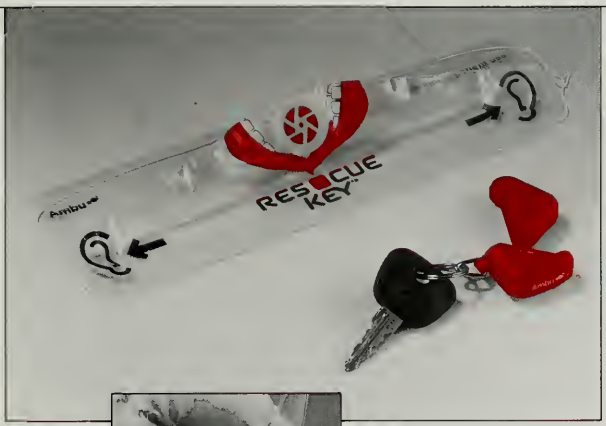

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viding a safe environment for the delivery of the antiviral agent.

The infant was tachypnic (75 breaths/min) with symmetrical chest excursion but 2+ substernal and intercostal retractions. Sinus tachycardia (210 beats/min) was observed on the cardiorespiratory monitor. The infant's skin was pale, cool, and dry, with no evidence of central cyanosis. Rectal temperature revealed persisting hypothermia (36.1°C).

In contemplating delivery of ribavirin in the incubator, I weighed the possibility of damaging the equipment during the aerosol therapy (and the consequent cost) against the clinical necessity of utilizing it. Of course, clinical necessity reigned, and ribavirin therapy was initiated according to physician order. Lyopholized ribavirin (6 g/300 mL sterile water) was nebulized 20 hours/day for 5 days at the prescribed F_{IO_2}. The ribavirin aerosol was delivered via a 72-inch nonheated-wire tubing inserted through the port hole proximal to the patient, replacing the heated humidification system's tubing. The SPAG-2 system (ICN Pharmaceuticals, Costa Mesa CA) was powered from a 50-psig outlet of the blender that formerly supplied the oxygen to the incubator. The oxygen analyzer remained within the system to monitor the F_{IO_2} delivered during the therapy. Care was taken not to add additional humidity through the incubator. The only filter, a gas inlet filter, was inspected by respiratory personnel every 8 hours for evidence of crystallization. The incubator's warming function was closely monitored for signs of malfunction. Each day, after the completion of the 20 hours of therapy, the infant was swaddled and briefly removed from the incubator. This allowed sufficient time for the internal portion of the incubator to be wiped with alcohol to remove any precipitate and for the linens to be changed. The passover heated-humidification system, previously described, was utilized between therapeutic regimens to maintain the F_{IO_2}.

Of course, safety of the staff members who administered the therapy was not overlooked. Prior to the initiation of ribavirin therapy, the patient was placed in a negative-flow room. All personnel entering the room were required to gown and wear a disposable high-efficiency respirator mask.

After 5 days of ribavirin therapy, the infant's respiratory status was greatly improved. The patient was weaned from oxygen and was able to maintain an S_{aO_2} well above 92%. However, the hypothermia persisted, and the patient was transferred to another incubator.

The incubator utilized during ribavirin administration was cleaned according to isolation protocol and sent to the biomedical department for performance inspection. The inspection failed to produce evidence of medication crystallization other than that on the interior surface of the incubator. The inlet filter was removed and sent for resistance analysis. No evidence of crystallization was detected, and zero flow differential was found between the filter before and after use with ribavirin therapy.

Although an extensive clinical investigation would be necessary for proof, our preliminary results suggest that ribavirin can be safely delivered in an incubator. Our experience—with the need to explore alternatives, seek solutions, devise alternatives, and demonstrate safety and effectiveness—is an example of the 'research' that respiratory care practitioners are called upon to do on a routine basis. It is the challenge to create a functional apparatus from our endless mounds of adapters that truly makes respiratory care a perfect blend of art and science.

Because of the relatively few cases of RSV seen in our institution, it is not feasible to conduct a more extensive study, but this report of our experience may assist other practitioners faced with similar situations. More importantly it may inspire in-depth investigation by practitioners on that never-ending search to improve patient care.

Terry Volsko BS RRT
NICU & Pediatric Supervisor
Respiratory Services
St Elizabeth Hospital
Medical Center
Youngstown, Ohio

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AARC & AFFILIATES

March 10-11 in Newport, Rhode Island. The RISRC holds their Newport Challenge Conference at the Newport Islander Doubletree Hotel on Goat Island. This conference is organized as a vehicle to provide physicians, nurses, and respiratory care practitioners with new attitudes and innovative ideas in health promotion and care, update in techniques, and a forum for sharing experiences and ideas. Includes lecture sessions and question-and-answer periods. Contact Nancy Roman at (401) 737-7010, ext 1618.

March 10-12 in Tahoe, Nevada. Chapter 9 of the CSRC and the American Lung Association of Alameda County return to South Shore Lake Tahoe and Caesar's for their 15th Annual Tahoe Conference. Topics covered include infectious diseases, transplantation, future team approaches, and high-tech in respiratory care. Plus, a neonatal/pediatric brown bag lunch presented by Children's Hospital-Oakland. Contact Barbara Banks-Norton at (510) 275-8287 or Carrie Smith at (510) 893-5474.

March 30 — AARC Videoconference. The AARC, in conjunction with VHA Satellite Network, presents the second of a 6-part videoconference series titled "Professor's Rounds in Respiratory Care." The second presentation, "Application of Positive Airway Pressure without Intubation," features Robert M Kacmarek PhD RRT, and David J Pierson MD. Call (214) 830-0061.

April 12-14 in Bismarck, North Dakota. The NDSRC hosts its Annual Convention featuring Deborah Cullen EdD RRT, Dean Hess MEd RRT, Robert Kacmarek PhD RRT, George Burton MD, and Beth Roark RRT. Topics include neonatal/pediatric/adult ICU topics, therapist-driven protocols, research in respiratory care, and HHN vs MDI controversy. Call (701) 224-7870.

April 13-15 in Gatlinburg, Tennessee. The TSRC presents its Annual Convention and Exhibition, "Walk on the Wild Side," at the River Terrace Resort. Scheduled speakers are John Hiser MEd RRT, Tommy Rust MEd RRT, Sam Giordano MBA RRT, Bob Kacmarek PhD RRT, Jim Fink RRT, Beth Roark RRT, Larry Gentilello, Brian Carlin MD, Patrick Dunne MEd RRT, John Walton MBA MHA RRT, and Damon Lawson RRT. Topics include test-taking techniques, transitions in health care, professionalism, mechanical ventilation, augmented CPT, therapist-driven protocols, nosocomial infections, neonatal ventilation, and line management. For registration information, call Colleen Schabacker at (615) 384-1569. For information on exhibits, call Candy Partee at (615) 443-6816.

April 13-16 in Cincinnati, Ohio. The Ohio, Kentucky, and Indiana Societies host the 20th Annual Region II for Respiratory Care Meeting, "Going Platinum!" at the Albert B Sabin Convention Center and Hyatt Regency Hotel. Contact Dave Dunlap, Chair, at (606) 292-4271 (Monday and Friday) or (606) 344-2058 (Tuesday, Wednesday, Thursday).

April 26-28 in Philadelphia, Pennsylvania. The PSRC presents its 28th Annual Conference and Exhibition at the Adam's Mark Hotel. This year's theme is "Respiratory All-Stars: Building Pride through Teamwork." The Pennsylvania State Sputum Bowl Finals are featured. Contact Betsy Schneck at (215) 829-3578 or Kathy Yandle at (215) 453-4517.

May 4-5 in Industry Hills, California. Chapter 4 of the CSRC and Kaiser Permanente host the 3rd Annual Neonatal Pediatric Pulmonary Care Conference and Golf Tournament at the Sheraton Hotel. Featured topics include Pediatric Radiology, ECMO in Infants and Children, A Rational Approach to Pediatric Ventilation, Is It Heart Disease or Lung Disease?, PPHN—What's New Besides the Name? For information, call the CSRC Chapter 4 hotline at (213) 727-CSRC.

May 19-21 in Jekyll Island, Georgia. The Georgia/South Carolina Region VI committee presents its Annual Conference and Assembly at the Holiday Inn. Topics include analgesia sedation and paralysis, emergency airway care, resonant ventilation of the lungs, lung transplantation, controversies surrounding circuit changes, and advances in antimicrobial therapy. Contact Bob Barber, Spartanburg Regional Medical Center, 101 East Wood St, Spartanburg SC 29303. (803) 591-6524.

May 22-25 in Spokane, Washington. The Respiratory Care Society of Washington presents the 20th Annual Pacific Northwest Regional Respiratory Care Conference at Cavanaugh's Inn at the Park. Specialty sections focusing on pediatrics, management, pulmonary functions, critical care, and computers are planned. A postgraduate pulmonary physiology course, panel discussion on hospital restructuring, special moonlight cruise, and statewide Sputum Bowl finals are scheduled. This is the

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OTHER MEETINGS

March 11-13 in Washington, DC. The National Association of Medical Directors of Respiratory Care (NAMDRC) presents its 16th Annual Meeting at the Stouffer Mayflower Hotel. For more information, contact the NAMDRC Executive Office at 5454 Wisconsin Ave, Suite 1340, Chevy Chase MD 20815. (301) 718-2975.

March 16-17 in Durham, North Carolina. The 7th Annual Cardiopulmonary Technology Seminar, sponsored by Duke University Medical Center, Durham Technical Community College, and the Respiratory Care Departments of UNC Hospitals and Durham Regional Hospital, is held at the Omni Durham Hotel and Convention Center. Contact Susan Rinaldo-Gallo at (919) 681-2720 or Chuck Alford at (919) 470-5366.

March 24-27 in Helena, Montana. The American Lung Association of Montana presents the Twelfth Annual Big Sky Pulmonary Ski Conference. Contact the American Lung Association of Montana, 825 Helena Ave, Helena MT 59601. (406) 442-6556, fax (406) 442-2346.

March 26 in Rosemont, Illinois. Triton College's respiratory care program and the Continuing Education Center for Health Professionals present "Pioneers and Progress" at the Holiday Inn O'Hare. The distinguished faculty will include respiratory care pioneers Forrest Bird, Jack Emerson, H Frederic Helmholz, E Trier Mörch, and Philip von der Heydt. Contact Wanda M Manning at (708) 456-8005.

March 26-28 in Nashville, Tennessee. The Association of Polysomnographic Technologists hosts the First Annual Spring Review Course in Advanced Polysomnographic Technology at the Opryland Hotel. Contact Todd Eiken, APT Education Chair, at (205) 592-5650.

April 20-21 in Little Rock, Arkansas. Respiratory Care Services of Arkansas Children's Hospital presents its Annual Pediatric/Neonatal Cardiopulmonary Care Conference. Special sessions focus on current and future trends in asthma treatment and education, metabolic monitoring in the ICU, primary pulmonary hypertension in newborns, and other issues. The meeting also features poster sessions and roundtable discussions. Contact Mike Anders RRT or Shelley Dedman RRT, Respiratory Care Services, Arkansas Children's Hospital, 800 Marshall St, Little Rock AR 72202. (501) 320-3535.

April 22-23 in Napa, California. The California Society for Pulmonary Rehabilitation hosts its 4th Annual Conference, "Rising To the Future," at the Inn of Napa Valley. Contact Gerilynn Connors BS RRT, or Kathleen Morris RN MS RRT at (707) 963-6588.

May 16-19 in San Francisco, California. The American Lung Association and American Thoracic Society host an International Conference. Vital information on the prevention and control of lung disease is presented in a variety of symposia and workshops. Contact Maureen J O'Donnell, American Lung Association, 1740 Broadway, New York NY 10019-4374.

October 24-29 in Jerusalem, Israel. The XIVth World Congress of Asthmalogy convenes in Jerusalem. Topics presented include molecular biology in lung disease, cells involved in asthma, and the house-dust mite and asthma. Abstracts are currently being accepted. Contact Gil-Kenes, 1617 JFK Blvd, Suite 946, Philadelphia PA 19103. (800) 223-3855.

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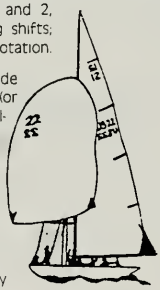

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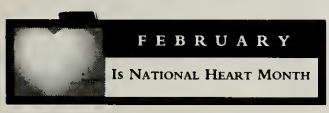

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CORRECTION

In the January 1993 issue of the journal, an error was made in Figure 1 of William Howard's paper "Pressure-Control Ventilation with a Puritan-Bennett 7200a Ventilator: Application of an Algorithm and Results in 14 Patients" (Respir Care 1993;38:34). We regret the error and encourage you to make the correction directly to your original figure.

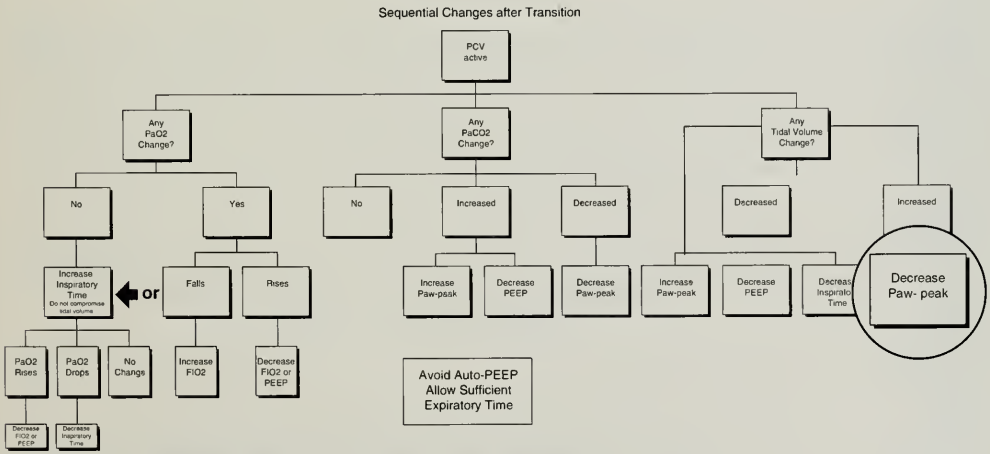

Fig. 1. Algorithm for managing patients on pressure-controlled ventilation.

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- Application of Positive Airway Pressure Without Intubation — Clinical Focus
  March 30, 1993: 12:30 p.m. to 2 p.m. EST — David J. Pierson, MD, and Robert M. Kacmarek, PhD, RRT
- Therapist-Driven Protocols in Respiratory Care — Respiratory Care Issues
  May 13, 1993: 12:30 p.m. to 2 p.m. EST — Sam P. Giordano, MBA, RRT, and George G. Burton, MD
- Monitoring Oxygenation in the Critically Ill Patient — Clinical Focus
  July 29, 1993: 12:30 p.m. to 2 p.m. EST — David J. Pierson, MD, and Leonard D. Hudson, MD
- Pulmonary Function Testing — When, Why, and What? — Clinical Focus
  September 30, 1993: 12:30 p.m. to 2 p.m. EST — David J. Pierson, MD, and Charles G. Irvin, PhD
- Unconventional Methods for Adult Oxygenation and Ventilation Support — Clinical Focus
  December 2, 1993: 12:30 p.m. to 2 p.m. EST — David J. Pierson, MD, and James K. Stoller, MD

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1993 Professor's Rounds in Respiratory Care

Part II: Application of Positive Airway Pressure Without Intubation — March 30 (Clinical Focus)
This program provides an overview of an expanding area of respiratory care. The session will cover short-term application in the inpatient setting in the treatment of acute, life-threatening conditions (e.g., mask CPAP for hypoxemic respiratory failure and nasal IPPV for acute ventilatory failure), and also elective, long-term application in home care (e.g., nasal CPAP for obstructive sleep apnea, and nasal IPPV for resting the ventilatory muscles). Mr. Kacmarek also will discuss the role of bi-level positive airway pressure via BiPAP device in inpatient and home care settings.

Part III: Therapist-Driven Protocols in Respiratory Care — May 13 (Respiratory Care Issues)
Therapist-driven protocols can allow practitioners to provide better patient care and contain costs. However, physician and administration resistance and the challenge of maintaining a highly motivated and educated staff can make implementing the protocols a difficult process. Through this program, viewers will learn how to gain the support of the medical director, physicians, administration, staff, and nursing departments. Will also describe how to overcome legal and time constraints, meet JCAHO requirements, and assign responsibilities.

Part IV: Monitoring Oxygenation in the Critically Ill Patient — July 29 (Clinical Focus)
This session will review the determinants of tissue oxygenation in the critically ill patient and the techniques available to the clinician for assessing these at the bedside. Dr. Hudson will discuss the current controversy about "supply dependency" of tissue oxygen utilization in ARDS and how it affects management. The program also will describe the different approaches to monitoring oxygenation advocated by authorities in different centers.

Part V: Pulmonary Function Testing — When, Why, and What? — September 30 (Clinical Focus)
This program is a discussion for clinicians aimed at clarifying the reasons for ordering PFTs and how to interpret their results. Included will be the clinical settings in which assessment of pulmonary function is most helpful in patient management. The session will also cover the rationale for exercise testing in pulmonary patients, selection of the appropriate technique for lung volume measurement, assessment of bronchodilator response, and how to determine whether a patient can withstand pneumoncetomy or lobectomy.

Part VI: Unconventional Methods for Adult Oxygenation and Ventilation Support — December 2 (Clinical Focus)
This session provides an overview of new and experimental techniques for adult oxygenation and ventilation support. Dr. Stoller will discuss the techniques' theoretical rationale, method of application, and experimental evidence of effectiveness. Among the techniques he will discuss are airway pressure release ventilation, proportional assist ventilation, extracorporeal CO_2 removal and intravascular oxygenation. The program will also consider the use of permissive hypercapnia as a ventilation strategy.

PRESENTERS

David J. Pierson, MD, Moderator — Medical Director of Respiratory Care, Harborview Medical Center, Seattle, WA, and Professor of Medicine (Pulmonary and Critical Care), University of Washington, Seattle, WA.

Sam P. Giordano, MBA, RRT, Moderator — Executive Director, American Association for Respiratory Care, Dallas, TX.

Charles G. Irvin, PhD — Director of Pulmonary Physiology, National Jewish Center for Immunology and Respiratory Medicine.

George G. Burton, MD — Chief-of-Staff-elect, Kettering Medical Center, Institute of Respiratory Diseases, Kettering, OH, Medical Director, Respiratory Therapy Program, Member Board of Directors, Kettering College of Medical Arts, Kettering, OH, and Clinical Professor of Medicine, Wright State University, Dayton, OH.

James K. Stoller, MD — Head of Respiratory Care, The Cleveland Clinic Foundation, Cleveland, OH.

Leonard D. Hudson, MD — Head of Pulmonary and Critical Care Medicine, Harborview Medical Center, Seattle, WA, and Professor of Medicine, University of Washington, Seattle, WA.

Robert M. Kacmarek, PhD, RRT — Director of Respiratory Care, Massachusetts General Hospital, Boston, MA, and Assistant Professor of Anesthesia, Harvard Medical School, Boston, MA.

Mitch Galloway — Senior Administrative Adviser, Bishop Clarkson Hospital, Omaha, NE.

1993 Call for Abstracts

RESPIRATORY CARE • OPEN FORUM

The American Association for Respiratory Care and its science journal, RESPIRATORY CARE, invite submission of brief abstracts related to any aspect of cardiorespiratory care. The abstracts will be reviewed, and selected authors will be invited to present papers at the OPEN FORUM during the AARC Annual Meeting in Nashville, Tennessee, December 11-14, 1993. Accepted abstracts will be published in the November 1993 issue of RESPIRATORY CARE. Membership in the AARC is not necessary for participation.

Specifications—READ CAREFULLY!

An abstract may report (1) an **original study,** (2) the **evaluation of a method or device,** or (3) a **case or case series.** Topics may be aspects of adult acute care, continuing care/ rehabilitation, perinatology/pediatrics, cardiopulmonary technology, health occupations education, or management of personnel and health-care delivery. The abstract may have been presented previously at a local or regional—but not national—meeting and should not have been published previously in a national journal. The abstract will be the only evidence by which the reviewers can decide whether the author should be invited to present a paper at the OPEN FORUM. Therefore, *the abstract must provide all important data, findings, and conclusions.* Give specific information. Do not write such general statements as "Results will be presented" or "Significance will be discussed."

Essential Content Elements

An **original study** abstract *must* include (1) Introduction: statement of research problem, question, or hypothesis; (2) Method: description of research design and conduct in sufficient detail to permit judgment of validity; (3) Results: statement of research findings with quantitative data and statistical analysis; (4) Conclusions: interpretation of the meaning of the results. A **method/device evaluation** abstract *must* include (1) Introduction: identification of the method or device and its intended function; (2) Method: description of the evaluation in sufficient detail to permit judgment of its objectivity and validity; (3) Results: findings of the evaluation; (4) Experience: summary of the author's practical experience *or* a notation of lack of experience; (5) Conclusions: interpretation of the evaluation and experience. Cost comparisons should be included where possible and appropriate. A **case report** abstract *must* report a case that is uncommon or of exceptional teaching/learning value and must include: (1) case summary and (2) significance of case. Content should reflect results of literature review. The author(s) should have been actively involved in the case and a case-managing physician must be a co-author or must approve the report.

Abstract Format and Typing Instructions

Accepted abstracts will be photographed. First line of abstract should be the title in all capital letters. Title should explain content. Follow title with names of all authors (including credentials), institution(s), and location. Underline presenter's name. Type or electronically print the abstract *single spaced in the space provided on the abstract blank.* Insert only one letter space between sentences. Text submission on diskette is encouraged but must be accompanied by a hard copy. Identifiers will be masked (blinded) for review. Make the abstract all one paragraph. Data may be submitted in table form *and simple figures may be included provided they fit within the space allotted. No* figures, illustrations, or tables are to be attached to the abstract. Provide all author information requested in right column of abstract form. A clear photocopy of the abstract form may be used. Standard abbreviations may be employed without explanation. A new or infrequently used abbreviation should be preceded by the spelled-out term the first time it is used. Any recurring phrase or expression may be abbreviated if it is first explained. Check the abstract for (1) errors in spelling, grammar, facts, and figures; (2) clarity of language; (3) conformance to these specifications. An abstract not prepared as requested may not be reviewed. Questions about abstract preparation may be telephoned to the editorial staff of RESPIRATORY CARE at (214) 243-2272.

Deadlines

The mandatory Final Deadline is June 7 (postmark). Authors will be notified of acceptance or rejection by *letter only*— to be mailed by August 15. Authors may choose to submit abstracts early. Abstracts received by March 19 will be reviewed and the authors notified by April 24. Rejected abstracts will be accompanied by a written critique that should in many cases enable authors to revise their abstracts and resubmit them by the final deadline (June 7).

Mailing Instructions

Mail (Do not fax!) 2 clear copies of the completed abstract form and a stamped, self-addressed postcard (for notice of receipt) to:

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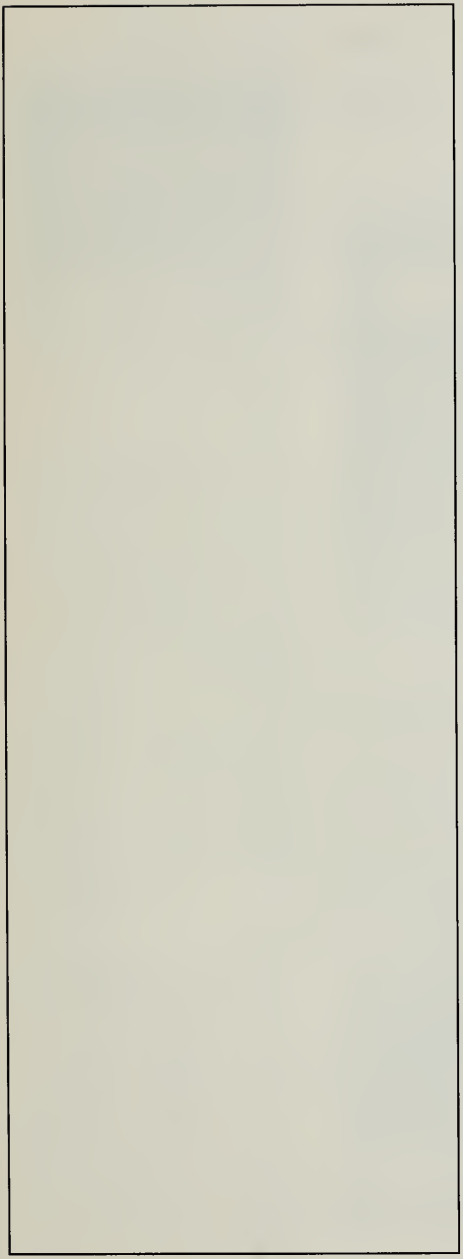
1993 Respiratory Care Open Forum

Abstract Form



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Final deadline is June 7, 1993
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Notices

Notices of competitions, scholarships, fellowships, examination dates, new educational programs, and the like will be listed here free of charge. Items for the Notices section must reach the Journal 60 days before the desired month of publication (January 1 for the March issue, February 1 for the April issue, etc). Include all pertinent information and mail notices to RESPIRATORY CARE Notices Dept, 11030 Ables Lane, Dallas TX 75229-4593.

The American Respiratory Care Foundation Awards for 1993

1. $2,000 for the best original paper (study, evaluation, or case report) *accepted* for publication from December 1992 through October 1993. This award is *not* limited to papers based on OPEN FORUM presentations.
2. Four awards of $1,000 each for papers *accepted* for publication from November 1992 through October 1993 based on *any* OPEN FORUM presentation (not limited to 1992 OPEN FORUM).
3. Five awards of $500 each for the best papers *submitted* (not necessarily published) by 1993 OPEN FORUM participants who have 'never published' in the Journal. The never-published first author must present the abstract at the Annual Meeting and must submit a paper based on the abstract before the 1993 Annual Meeting (*received* in the Editorial Office by November 1, 1993). Co-authors may have previously published in RESPIRATORY CARE.

Three awards of $333 each are to be awarded to the authors of the three best features from Test Your Radiologic Skill, Blood Gas Corner, Kittredge's Corner, and PFT Corner accepted for publication from November 1992 through October 1993. All three (or none) of the features may be chosen from a specific category (eg, all three may be chosen from Blood Gas Corner).

Registration Reimbursement

As in the past, any 1993 OPEN FORUM presenter (or co-author designee) will receive complimentary registration for an adequately prepared paper based on his 1993 OPEN FORUM abstract, submitted prior to or at the 1993 Annual Meeting.

All awards will be made at the 1993 Annual Meeting. Papers are judged automatically. No application is necessary.

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Applications Accepted Beginning:	November 1, 1992
Application Deadline:	January 1, 1993

RRT Examination

EXAMINATION DATE:	JUNE 5, 1993
Applications Accepted Beginning:	December 1, 1992
Application Deadline:	February 1, 1993

CPFT Examination

EXAMINATION DATE:	JUNE 5, 1993
Applications Accepted Beginning:	December 1, 1992
Application Deadline:	April 1, 1993

Perinatal/Pediatric Specialty Examination

EXAMINATION DATE:	MARCH 13, 1993
Applications Accepted Beginning:	September 1, 1992
Application Deadline:	November 1, 1992

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CPFT Recredentialing:	$25.00	$ 80.00
RPFT Recredentialing:	$25.00	$130.00
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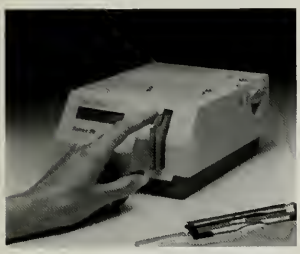

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3 ❑ Hosp 200 to 299 beds
4 ❑ Hosp 100 to 199 beds
5 ❑ Hosp <100 or less bed
6 ❑ Skilled Nursing Facility
7 ❑ Home Care Practice
8 ❑ School

II. Department
A ❑ Respiratory Therapy
B ❑ Cardiopulmonary
C ❑ Anesthesia Service
D ❑ Emergency Dept

III. Specialty
1 ❑ Clinical Practice
2 ❑ Pennatal Pediatrics
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4 ❑ Clinical Research
5 ❑ Pulmonary Function Lab
6 ❑ Home Care/Rehab
7 ❑ Education
8 ❑ Management

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C ❑ Supervisor
D ❑ Staff Technician
E ❑ Staff Therapist
F ❑ Educator
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156	157	158	159	160	161	162	163	164	165	166	167	168	169	170
171	172	173	174	175	176	177	178	179	180	181	182	183	184	185
186	187	188	189	190	191	192	193	194	195	196	197	198	199	200

I. Type of Instn/Practice
1 ❑ Hosp ≥ 500 or more beds
2 ❑ Hosp 300 to 499 beds
3 ❑ Hosp 200 to 299 beds
4 ❑ Hosp 100 to 199 beds
5 ❑ Hosp <100 or less beds
6 ❑ Skilled Nursing Facility
7 ❑ Home Care Practice
8 ❑ School

II. Department
A ❑ Respiratory Therapy
B ❑ Cardiopulmonary
C ❑ Anesthesia Service
D ❑ Emergency Dept

III. Specialty
1 ❑ Clinical Practice
2 ❑ Pennatal Pediatrics
3 ❑ Critical Care
4 ❑ Clinical Research
5 ❑ Pulmonary Function Lab
6 ❑ Home Care/Rehab
7 ❑ Education
8 ❑ Management

IV. Position
A ❑ Dept Head
B ❑ Chief Therapist
C ❑ Supervisor
D ❑ Staff Technician
E ❑ Staff Therapist
F ❑ Educator
G ❑ Medical Director
H ❑ Anesthesiologist
I ❑ Pulmonologist
J ❑ Other MD
K ❑ Nurse

V. Are you a member of the AARC?
1 ❑ Yes 2 ❑ No

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